Supreme Court, U.S.
FILED

No. 09-734

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In The

Supreme Court of the United States

GEOFFREY S. AMES, M.D.,

Petitioner,

vs.

WASHINGTON STATE HEALTH DEPARTMENT
MEDICAL QUALITY HEALTH ASSURANCE COMMN.,

Respondent.

On Petition For Writ Of Certiorari To The Supreme Court Of The State Of Washington

PETITION FOR A WRIT OF CERTIORARI
and
APPENDIX, PART ONE

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QUESTIONS PRESENTED

Is it constitutional under *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), under 21 U.S.C. §396, and/or under the law of federal preemption generally, and does it meet minimal standards of rationality under the Due Process Clause of the Fourteenth Amendment, for a State to make evidence that an FDA-cleared device was not submitted and cleared for a particular use, sufficient in itself to establish that the device is not effective for that use and the user guilty of negligence?

Is it consistent with the Due Process Clause of the Fourteenth Amendment:

1. for a state administrative agency to enter an order in which findings of fact essential to liability are not based on record evidence, because those facts can only be established by expert testimony, and the agency claims to have the necessary expertise, and needs no assistance to determine them – *i.e.*, should this Court resolve the conflict in the lower courts over the validity of the so-called *Jaffe* doctrine by declaring it unconstitutional and reversing the decision below?

2. for a state administrative agency to discipline a licensed professional for alleged conduct that was not charged in the pleadings or argued before or at

QUESTIONS PRESENTED – Continued

the hearing and which was never identified as the ground for liability until the agency published its decision finding the conduct unprofessional?

3. for state appellate courts to uphold the actions of a state administrative agency on factual and evidentiary grounds that the agency itself did not accept, on findings that the agency did not make, and in fact rejected, and that substitute the court's lay perceptions and conceptions on technical issues for the expert judgments of the agency to which those courts say they defer?

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PETITION FOR A WRIT OF CERTIORARI

Geoffrey S. Ames, M.D. respectfully petitions this Court for a writ of certiorari to review the judgments of the Supreme Court and the Court of Appeals, Division III of the State of Washington.

OPINIONS BELOW

The opinion of the Supreme Court of Washington is reported at 166 Wash.2d 255 (2009). The opinion of the Court of Appeals, a letter opinion of the Superior Court of Benton County, Washington and the Findings of Fact, Conclusions of Law and Final Order of the Medical Quality Assurance Commission ("Order") are unpublished. The opinions and Order appear in the Appendix. App.1,15,33,42.

JURISDICTION

The judgment of the Supreme Court of Washington was entered on June 6, 2009. Petitioner's timely motion for reconsideration, App.397-98, was denied on September 18, 2009. App.65. The jurisdiction of this Court arises under 28 U.S.C. §1257(a).

STATUTES AND CONSTITUTIONAL PROVISIONS INVOLVED

21 U.S.C. §337(a)

[All] proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States.

21 U.S.C. §396

Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.

United States Constitution

Article VI, second paragraph

This Constitution, and the laws of the United States which shall be made in pursuance thereof; . . . shall be the supreme law of the land; and the judges in every state shall be bound thereby. . . .

Amendment XIV, sec. 1

No State shall . . . deprive any person of life, liberty or property, without due process of law.

STATEMENT

A State Medical Board Initiates a Proceeding to Enforce the FDCA and a State Supreme Court Holds Off-Label Use of an FDA-Cleared Device Sufficient to Establish Its Inefficacy and the User's Negligence

A state medical board brought charges against a holistic physician for violating the United States Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §301 et seq. CR 3; App.66. The statement of charges alleged that he had tested a patient for food allergies with "an electrodiagnostic device" that had not been cleared by the Food and Drug Administration ("FDA"). *Id.* at ¶1.2. Alternatively, it alleged that if the device had been cleared by the FDA under a different name the physician had violated the act, because he had used it for a purpose that the FDA had not cleared. ¶¶1.6, 1.11. The charges also contained a count for violating the state food and drug law, but this was based on the federal violation. A device is "adulterated" under the FDCA if it is introduced into interstate commerce without being approved, exempted or cleared; so, the charges alleged, by using a device not sanctioned by the FDCA, the physician had used an adulterated device under state law. CR 4; App.68.

There was no allegation that the physician had been found by the FDA or any court, federal or state, to have violated the FDCA, nor that the FDA had ever complained about, let alone taken any regulatory action against the physician, the manufacturer and seller of the device or the device itself. App.3-5. When

the issue was adjudicated, no evidence of such action was offered and the manufacturer testified that the FDA, with whom he worked regularly, had never objected to his marketing of the device. CR 2806,2838-39,2855-58,2871-73,2881; App.260-62,273-75,281-84,289.

This was, thus, an original state administrative proceeding in which the board proposed to adjudicate federal questions under, *e.g.*, 21 U.S.C. §§360e(b)(1)(A), 360e(b)(1)(b), 360c(E)(i), 360k, 331(c). *See Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 345-346 (2001). These violations were asserted to be unprofessional conduct solely because Washington law prohibits health care providers from violating any state or federal statute "defining or establishing standards of patient care or professional conduct or practice." RCW 18.130.180(7). App.415,68.

The charges were later amended to claim that the alleged FDCA violation fell not only under RCW 18.130.180(7), but under §§(1), (4), and (16) of the statute, which proscribe moral turpitude, negligence and "promotion for personal gain" of an "inefficacious" device. CR 60,62; App.70,73-75,415. In its answer to the new charges, the physician challenged the good faith of the proceeding, and alleged that it violated, *inter alia*, the due process, equal protection and supremacy clauses of the U.S. Constitution. CR 205-06,208; App.78,81.

Although the amended statement invoked three new sections of the disciplinary law, neither of its two

new paragraphs of factual allegation charged new culpable conduct. There was no charge that any of the conduct was injurious or deceptive, that it created a risk of harm or that it fell below the standard of care. The only culpable conduct charged in the amended statement with the two new paragraphs was the alleged violation of the FDCA by receiving and using the device. App.73-75; *see* CR 2167-68; App.356-57.

Throughout the prehearing proceedings and through the beginning of the hearing, both parties and the presiding officer understood – with a minor addition that was quickly eliminated – the theory of the charges to be that all of the violations turned upon whether the FDCA had been violated. *See* CR 1394-96,2052-58,965; App.105-112,99-100. In other words, because, allegedly, the FDCA did not permit him to use the device, the physician had acted immorally, negligently and had "promoted" an inefficacious device. In his opening statement at the hearing, for example, the board's counsel declared that the entire case would turn upon the testimony of his FDA expert and that the physician's defense would be that there was no FDCA violation, because his use of the device was a permissible "off-label" one. CR 2056-58; App.107-112.

Before the hearing, Petitioner moved to dismiss under the supremacy clause, because the proceeding violated and conflicted with the FDCA, FDA regulations and with this Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Its continuance in an incompetent tribunal, it was urged,

deprived him of liberty and property without due process of law. CR 354-358; App.90-96. The motion was denied. *E.g.*, CR 1180; App.97-98.

At the hearing, all of the federal charges and issues were adjudicated by a panel consisting of a physician, a physician's assistant and a public member. CR 1850; App.42-43. The panel found that the only witness offered to establish that the physician's particular device had not been cleared knew nothing about it and thus that the board had no evidence that it had not been cleared. CR 1853; App.45-47. The panel found that the device had been marketed legally and the FDCA had not been violated. CR 1853,1863; App.45-47,57-58. It found that the physician had been using the device for a purpose not covered by the FDA clearance – *i.e.*, "off-label" – but it did not find this an FDCA violation either. *Ibid.* Although the board threw the FDCA charges out, the decision was based on the facts, and did not disclaim authority to bring other such cases. CR 1853; App.45-47.

The FDCA grounds had been the entire basis of the charges until the evidentiary hearing was under way, but in its Final Order, the board announced grounds for proceeding against the physician for conduct that had not been alleged in the statement of charges. Compare CR 60-63 with CR 1861-62; App.70-73,55-57. It found, *inter alia*, that the device was "inefficacious," because it had indicated the patient had an egg allergy which, it asserted, he did not have, that the physician had treated the patient for the

allergy and told him he had been cured, when he could not have been, thereby creating an unreasonable risk of harm. In addition, it found that at the time he purchased the device the physician (who had been using it with fifty percent of his patients for four years when he first saw the patient) had not adequately investigated its safety. App.56. It did not find, however, that the device posed any safety risk, and the evidence on both sides was that the device was harmless. CR 2879-81,2283,295-96; App.287-90,169-70. Using an inefficacious device was held to be *ipso facto* an act of negligence and recommending the acupressure allergy therapy with which it was used to be illegal "promotion for personal gain" of an "inefficacious" device. App.56-57. It, apparently, but not explicitly, was also found that the assertedly inadequate investigation was negligence, as well. *See* App.58,¶2.3.

Thus, the FDCA and the FDA's actions and processes seemed to be out of the case. They were not mentioned in the opinion of the Superior Court and were not deemed relevant by the Court of Appeals, although it mistakenly stated that the device purchased by the physician had not been cleared. App.33-41,23. But after the state Supreme Court accepted review of the physician's appeal, to consider due process issues related to record evidence and notice of charges, that Court brought the FDCA and FDA back in. *Ames v. Medical Commission*, 166 Wn.2d 255, 262-263, 208 P.3d 549, 552 (2009). Because this could not be anticipated, supremacy and due process clause

challenges were raised by a Motion for Reconsideration. App.397,399-401,402-405.

The Court ruled that the fact that the FDA clearance was not for the use the physician was making of the device, and that it was a use for which the maker had not submitted it, was sufficient to establish both that the device was inefficacious for that use and also that it was negligent to use the device in that way. App.9-10.

The Conflict About the Evidence That Due Process Requires in Agency Cases Against Professionals

When the board's FDCA theory collapsed at the hearing, it had no witness to testify that the device was "inefficacious" or that using it, even if it was inefficacious – no matter how good the anecdotal evidence for its effectiveness and whether it was used in good faith – in assessing allergies was *ipso facto* negligence and a violation of the statute prohibiting "promotion for personal gain of" an "inefficacious" device. Because these are matters of scientific, technical and medical expertise, they would have required that such testimony be given by experts in the relevant fields, *e.g.*, a physician specializing in allergies and/or a biomedical engineer expert in the operation of medical devices. *See* discussion below.

The board had called only four witnesses. Two of these were the physician, who contested the board's allegations on these issues, and the patient. CR 1851;

App.43. The others were an FDA employee who knew nothing about the status of the physician's device and an expert in biofeedback, named Richard Sherman. CR 1851,1853; App.43,46. He had been called to establish that what the physician was doing was not biofeedback, the use for which the device had been cleared. CR 1396,2299; App.105-06,180. His testimony was dismissed, because, the Order stated, "Dr. Sherman not only did not know about the LISTEN device, but also had not seen or evaluated it." App.46-47. This witness testified that he had never heard of the device before he had been contacted by the board's counsel, and when it was shown to him said, "I don't know what any of this is." CR 2297-98; App.178-79.

Nevertheless, without any testimony on the technical and medical issues in the case – or even reports of studies and tests establishing the device's ineffectiveness for the use the physician was making of it – the board found that the device was not efficacious and that using it was unprofessional conduct. It based this decision on its own expertise. CR 1852; App.45. The Analysis section of its Order anticipated objection. *Ibid.* "Expert testimony," it stated, "is helpful, but not essential to the Department's case, nor would the lack of such testimony either support or require dismissal of the charges against Respondent." Citing *Johnston v. Disciplinary Board*, 99 Wn.2d 466 (1983) and *Brown v. Dental Board*, 94 Wn.App. 7 (1995), it declared that because of its own

expertise, "No additional expert is necessary to resolve this case." *Ibid.*

Thus, contrary to what the state Supreme Court asserted in the opinion Petitioner asks this Court to review, the Order did not rely on the testimony of Petitioner's witness, Mr. Clark, or of Dr. Sherman, to support any of its findings or conclusions. *See generally* App.58,¶2.3. And neither of the other two courts considering the case ever said that it did either. *See* App.1-11,15-30 and discussion below.

Because of cases like *Johnston* and *Brown*, Washington is part of the significant minority of jurisdictions that follow the doctrine of *Jaffe v. State Department of Health*, 135 Conn. 339, 64 A.2d 330 (1949). In that case a physician was disciplined by a medical board for excessive charges, for negligence and incompetence without any testimony – expert or otherwise – as to why his charges were excessive, of what conduct or omissions his negligence consisted and of the defects in his education and experience that established incompetence. The evidence, to the extent there was any, was in the minds of the medical board and not available to the accused to rebut or explain. 135 Conn. at 345-47.

The Connecticut Supreme Court ruled that no such testimony was necessary, because it could only be given by experts; the board's members were experts; and they did not need and could freely disregard such testimony even if it were offered. 135 Conn. at 347, 349. It so held in spite of acknowledged

authority from this Court, that decisions based on evidence that is not on the record violate due process. *Id.* at 346; *see Interstate Commerce Commission v. Louisville & Nashville R. Co.*, 227 U.S. 88 (1913) ("due process of law [requires] that one called upon to answer shall be confronted with the evidence against him."); *see also Ohio Bell Telephone Co. v. P.U.C.*, 301 U.S. 292, 304, 57 S.Ct. 724, 730 (1937) (Cardozo, J.).

Be that as it may, adverse reaction to *Jaffe* was swift. *See, e.g., Smith v. Department of Registration & Ed.*, 412 Ill. 332, 106 N.E.2d 722 (Ill. 1952) ("The reasoning . . . [against] the Jaffe case, in our opinion is *sound and unanswerable*.") (emphasis added).

> *This startling theory,* if recognized, would not only render absolute a finding opposed to uncontradicted testimony but would render the right of appeal completely inefficacious as well. A board of experts, sitting in a quasi-judicial capacity, cannot be silent witnesses as well as judges. . . .
>
> The *very essence of due process* is the opportunity to hear and controvert the evidence upon which the issue presented is to be decided. Factual knowledge on that issue, expert or otherwise, of the triers of the facts is not evidence and cannot form the basis in whole or in part of the ultimate decision. Morgan v. U.S., 298 U.S. 468, 56 S.Ct. 906, 80 L.Ed. 1288 (1936). To sanction such practice would be to frustrate *the fundamental right to a hearing*.

New Jersey State Bd. of Optometrists v. Nemitz, 21 N.J.Super. 18, 28-30, 90 A.2d 740, 745-746 (N.J.Super.A.D. 1952) (emphasis added). By the 1980s, a clear majority of state courts addressing *Jaffe* had resoundingly rejected it. *See Arthurs v. Board*, 383 Mass. 299, 309-310, 418 N.E.2d 1236 (1981):

> The board may put its expertise to use in evaluating the complexities of technical evidence. *However, the board may not use its expertise as a substitute for evidence in the record.* "The requirement for administrative decisions based on substantial evidence and reasoned findings which alone make effective judicial review possible would become lost in the haze of so-called expertise (if material facts known to the agency did not appear in the record). Administrative expertise would then be on its way to becoming 'a monster which rules with no practical limits on its discretion.'" Baltimore & Ohio R. R. v. Aberdeen & Rockfish R. R., 393 U.S. 87, 92, 89 S.Ct. 280, 283, 21 L.Ed.2d 219 (1968), quoting from Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 167, 83 S.Ct. 239, 245, 9 L.Ed.2d 207 (1962).

See also, Drew v. Psychiatric Sec. Rev. Bd., 322 Or. 491, 498-499, 909 P.2d 1211, 1214-1215 (1996):

> [A] less flattering . . . summary of this last argument is as follows: "There's enough evidence but, even if it doesn't seem like enough to you – trust us. We have expertise beyond

> that of the average person in these cases, and we're satisfied." Seen in this light, it should come as no surprise that we reject the argument.
>
> * * * * [It is] fundamental . . . that fact-finding in contested cases is governed exclusively by the record of the hearing. * * * *[E]xclusiveness of the record is at the core of the right to a fair hearing. Without that principle the hearing itself can be but a sham.* * * * Only if the agency is limited to the record of the hearing can the private party have assurance that he not only has *a full opportunity to present his case but, more important, opportunity to confront and rebut the entire case against him.* [citing authority]. . . .

See generally Martin v. Sizemore, 78 S.W. 249, 271 (Tenn.Ct.App. 2001) for a list of the majority jurisdictions rejecting *Jaffe* and of the minority following it. Recent cases rejecting it include *Huff v. North Dakota State Board*, 690 N.W.2d 221, 227 (N.D. 2004) and *Kyu Son Yi v. State Board of Veterinary Medicine*, 960 A.2d 864 (Pa. Comwlth. 2008).

But *Jaffe* was reaffirmed by the Connecticut Supreme Court in *Levinson v. Connecticut Bd. of Chiropractic Examiners,* 211 Conn. 508, 560 A.2d 403 (1989) and remains "good" law in that state to this date. North Carolina having earlier rejected it, fairly recently adopted it again. *Leahy v. North Carolina Bd. of Nursing,* 346 N.C. 775, 488 S.E.2d 245, 248 (1997).

The Supreme Court of Washington, as its opinion states, took the appeal in this case primarily to revisit its decisions following *Jaffe*. App.7. But the Court not only reaffirmed its earlier precedents, but took them farther than any jurisdiction has ever expressly gone. *See* 166 Wn.2d at 261; App.7-8. ("Washington law does not require that expert testimony be provided to MQAC"). Although the court acknowledged that Petitioner was claiming "that the hearing he received was fundamentally flawed because the Department failed to offer expert testimony on the issues of standard of care and device efficacy," and "that our standard of review loses its meaning when at least some of the evidence is present only in the minds of the experts on MQAC's panel," 166 Wn.2d at 262; App.8, it did not expressly discuss any of the due process objections raised by the Petition for Review, even though they were the first issues raised, nor of any of the courts in the majority rejecting *Jaffe*, apparently acknowledging that "at least some of the evidence is present only in the minds of the experts" on the hearing panel. App.1-11.

Nor did it deny that the *Jaffe* doctrine affects the quality of judicial review. Petitioner had raised the process issues created by *Johnston* and *Brown* at the hearing, CR 2648-49; App.371-72, and the unconstitutionality under the Fourteenth Amendment of an order issued without evidence in its Petition for Review to the Benton County Superior Court. App.379,383-84,386. It raised, but did not expressly argue, the constitutionality of *Johnston* in its opening

brief in the Court of Appeals, Opening Brief, p. 24 n.16; App.407,408-09,411 n.16, because that Court did not have authority to overrule *Johnston*, a Supreme Court decision. In any event, the Washington court decided the issue, ruling that its precedent was not "fatally flawed in the way" Petitioner argued. 166 Wn.2d at 262; App.9.

The Statement of Charges That Did Not Allege the Facts on Which Liability Was Grounded and the Final Order That Ultimately Did

The first paragraph added to the charges by the amended statement recited that the patient had complained of chronic fatigue at his first visit to the physician on June 6, 2001 and that the physician had ordered blood, urine and hair tests on that date. App.72,¶1.13. The second new paragraph (¶1.14) described the events of the second visit when he used the device with the patient. App.72-73. In other words, it enlarged on the statement in the second paragraph of the charges, ¶1.2, which alleged that the physician had tested the patient on July 10, 2001 for food allergies "using an electrodiagnostic device." App.70. Paragraph 1.14 recited that the blood and other test results were discussed on that date and that the physician reported that the blood tests showed a number of food allergies. It then described how the device was used with the patient, showing that the device itself did not test for the allergy, but that it was used as part of a muscle test. App.72-73.

Prior to the hearing, see above, the entire case had been about the asserted FDCA violation, except for one brief attempt to make the hair test an issue that had been abandoned and did not appear in the board's opening statement. App.105,107-112. Both parties also understood that the misconduct being charged was using the device as part of a muscle test in connection with a suspected allergy. It was the testing that violated the various provisions cited in the statement of charges. This was the allegation in the charges; it was not changed by the prehearing statement; and was memorialized by the presiding officer. App.99,101,105.

Very soon after the hearing began, both the board's counsel and the physician's assistant sitting on the hearing panel tried by the questions they asked to enlarge the theory of the case – first to make it a case about the propriety of the other testing alleged and a recommendation that the patient undergo chelation (which was not alleged) and later – after the board's counsel had rested – about still other conduct, *e.g.*, whether the physician had adequately investigated the safety of the device. CR 2134-2138,2168,2263-2264,2677; App.350-57,361-63. No proposal, however, was made to amend the charges.

The physician and the presiding officer objected to these and other similar attempts to add theories of liability, each stating that due process barred the attempt to go beyond the pleadings at that stage in the proceedings. *Ibid*; CR 2264-67,2544-45,2575-76; App.361-65. The presiding officer expressly excluded

the argument that the physician had failed to adequately investigate the safety of the device, because it had not been alleged in the statement of charges, as administrative regulations, and, the presiding officer ruled generally, due process required. CR 2677. *See* WAC 246-11-250; App.416; CR 2575-76.

Nevertheless, when the Order was issued its findings were based on theories that had not been in the statement of charges. The most obvious was a finding, despite the P.O.'s ruling, that the physician had not adequately investigated the safety of the device. App.56,¶1.27. Less obviously, but more importantly, the theory of the physician's alleged misconduct with the patient was enlarged.

As we have seen, the Order finds that the patient did not have an egg allergy, that the physician therefore misdiagnosed him when he said he did, that he treated him for the allergy, told him that he had been cured when he had not been (apparently, because he did not have an egg allergy at all) and that all of these together created an unreasonable risk of harm. App.57,¶1.29.

None of these elements of the new theory of the physician's misconduct, which were grounded in the finding that there had been no egg allergy, had been pleaded in the statement of charges, even though if they had actually occurred, they would have been known to the board before the first charges were filed. App.70-74. In addition, the board's counsel in

argument specifically stated that the board did not know if the patient in fact had an egg allergy. CR 2551. In addition, they were not argued or asserted in the board's prehearing statement, the opening statement (as discussed above) or even in the board's closing argument. *See* references, *infra*.

REASONS FOR GRANTING REVIEW

This Court when it denies certiorari can usually feel comfortable that the petitioner has already had two or three reviews by appellate courts. In this case, however, Petitioner claimed below and insists here that he has never received the judicial review to which he was entitled from any of the courts to which he took his appeal. Meaningful review is a part of the due process right. *See, e.g., West Ohio Gas Co. v. P.U.C.*, 294 U.S. 63, 68-69 (1935). Washington law gives every licensed professional an absolute right to review on every traditional ground and thus the right becomes part of his property in the license. *See* RCW 34.05.570(3). In addition, when a party appears in an evidentiary hearing, even when he loses, he achieves various evidentiary and factual objectives, findings, concessions, admissions, and legal rulings which may on appeal create the basis for a reversal. If the appellate court disregards these litigation successes, especially as here when it decides factual and evidentiary matters differently from the fact-finder, then

the hearing that might have appeared adequate at the time, becomes a sham.

Petitioner contends that the quality of the opinions of all of the courts below and their disregard and contradiction, or failure to take account, of the findings and rulings of the factfinder and the explicit and implicit decisions it made about the weight and relevance of evidence is decisive proof that each of them did not give the attention to this case that must be given in reviewing a body that combines all of the major powers of government. Indeed, they abetted the agency's abuse of power by adopting rationales for it that even the agency had not advanced in its decision.

The Attempt to Use the FDCA and the FDA's Processes as the Basis for Finding Liability Is a Material and Obvious Interference in the Administration of the FDCA and Appears to Be a Clear Violation of 21 U.S.C. §396 and in Contravention of *Buckman*

What the highest Court of an important legal jurisdiction is saying is that using a device for a purpose for which it was not submitted to, or approved, by the FDA is enough to establish (a) that the device is inefficacious, and (b) that the user of the device is negligent. This gives an FDA decision not to clear or approve such use the effect of outlawing or, at least, materially deterring off-label uses, in contravention of *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 345-346 (2001) and 21 U.S.C. §396,

which protects the right of health care providers to use devices off-label.

Not only does the Court give unwarranted importance to the failure of approval by the FDA, but it appears to base its assertion that the device was not designed for the uses to which Dr. Ames and other practitioners of his form of acupressure make of it merely from the fact that it was not submitted to the FDA to be marketed for those purposes. There is no other evidence cited by the Washington court for its assertion that the device was not designed for those uses and the Order does not make such a finding. *See* App.42-63. The maker of the device expressly testified that it had a signal generator that was designed to do what the physician used it for – to emit the homeopathic electromagnetic fields of various substances. CR 2873-76,1854,¶1.1,2158-61,2173-79; App.283-87,47-48,¶1.1,129-133,136-142; *see* the Order's reference to the signal generator. CR 1855-56; App.48-51.

Thus, an opinion of a respected state high court became a precedent to be used in state tort actions and health care regulatory proceedings in which necessary evidence does not exist or is too weak to sustain the action. The opinion also gives legitimacy to the common misconception that failure to seek or to secure a clearance or an approval from the FDA for a particular device – or use of a device – means that the device is unsafe and/or ineffective, a misconception of federal law that can cause mischief in many venues, and which this Court can decisively

dispel if it takes this case and elaborates upon the message of the *Buckman* case.

Otherwise, the result for the FDA is that when it declines to approve, and especially when it declines to clear a device as substantially equivalent to a predicate device already on the market, that action will have consequences the agency may well not intend or want. Indeed, the board's FDA witness in this case and the maker of the device both testified that the agency actually helps companies get their products on the market when a particular use – which the FDA knows to be the one that the company has designed the product for – cannot be cleared, by suggesting that it narrow or limit its claims on the proposed labeling so that it can be cleared on the narrower basis. CR 2404-05,2871-72; App.209-11,281-83. Once on the market, as the FDA well knows, *see Buckman*, 531 U.S. at 350-51, the product could and will be used by providers for the uncleared purpose.

Under the Washington court's doctrine, manufacturers who have a device with a use that is promising, but not substantially equivalent to similar devices on the market, or not yet ready for the extensive and expensive testing required to obtain a premarket approval, will be able to get the device on the market with a narrower clearance, but their customers – the providers – will be deterred from using it. This will financially deter the manufacturer from seeking such clearances or delay their attempts to do so, thereby depriving patients and health care providers of what in many cases will be an important

modality. *See Buckman* at 350-51. This seems to fly in the face of 21 U.S.C. §396, which seems clearly to say that mere off-label use of a device shall not be considered unlawful.

Even if the Washington court's opinion were to be construed more narrowly, the fact that the device was not submitted or approved for an off-label use in a federal regulatory process is still an essential part of its holding, and the federal questions it thereby resolves are "interwoven" in the Court's decision. *See Michigan v. Long*, 463 U.S. 1032, 1041 (1983). Those are not likely to be susceptible to review by any federal court other than this one, because they would likely be raised only in actions brought by state agencies and in state courts.

In addition, if this Court grants review, it will then have the opportunity to address the propriety of the process by which the state agency obtained jurisdiction over Petitioner by prosecuting what was in reality a federal action that can only be brought in the name of the United States and in a federal court. 21 U.S.C. §337(a). This administrative maneuver seems a clear, unconstitutional interference in the administration of the FDCA, even more dramatically so than the one in *Buckman*. But it is a maneuver that can be used to – as it was here – achieve an impermissible aim, but escape review, because the agency can abandon the theory in its ultimate decision. It should be outlawed by this Court before it becomes a practice.

Adherence to the *Jaffe* Doctrine Not Only Denies the Notice, Hearing and Judicial Review Required by Due Process, But Is Literally an Invitation to the Kind of Tyranny That Most Concerned the Framers Before There Was a Bill of Rights

The requirement of expert testimony on the record when essential factual elements of a case cannot be established by a lay witness, not only allows the accused to see what the case is against him at the hearing, but, because the agency will have to identify the expert beforehand, to depose him, making meaningful the right to anticipate and prepare a defense. *See In re Ruffalo*, 390 U.S. 544 (1968) (In "adversary proceedings of a quasi-criminal nature" the "charge must be known before the proceedings commence.").

It is also an essential safeguard against administrative abuse of power, the potential tyranny that bureaucratic agencies can exercise because they combine legislative, executive and judicial powers. An agency can – as Petitioner contends happened here – implement a legislative policy that is stated in no law or regulation by initiating a quasi-judicial proceeding under a vague or literally overbroad statute without essential evidence and then in its judicial capacity find whatever evidence it had, or could acquire at the hearing, to be sufficient. *See Morrison v. Olson,* 487 U.S. 654, 697-702, 108 S.Ct. 2597, 2622-2625 (1988) (Justice Scalia, dissenting):

> The Framers . . . viewed the principle of separation of powers as the absolutely central guarantee of a just Government. . . . Without a secure structure of separated powers, our Bill of Rights would be worthless, as are the bills of rights of many nations of the world that have adopted, or even improved upon, the mere words of ours.

In this case, for example, the charges did not arise out of an actual complaint about the physician's use of his device. The patient testified that he had not made such a complaint and had not been injured or deceived by the physician or the device. CR 2227-28; App.155-57,152. Nor was there a claim or evidence that anyone else had complained or been harmed.

The patient's report was simply seized upon to justify suppression of the device, which the board assumed – erroneously – that the physician was using for electrodermal screening, a particular *bête noir* of anti-alternative medicine elements in medical boards around the country. CR 1396; App.105. *See, e.g.*, *Painter v. Abels*, 998 P.2d 931, 939 (Wyo. 2000), where a medical board attempted to prevent an alternative physician from using an EDS device like the one in this case by attacking her mental health and when that failed by claiming negligence without being able to offer any expert testimony to support the claim. Just as in *Painter*, where it was used for EDS, here the board could present no evidence that the device was not helpful the way the physician was using it. But the Wyoming court could see through

the board's case, whereas here the Washington courts desperately struggled to support it.

Requiring expert testimony insures that some independent authority must testify under oath to the theory under which the accused is ultimately held liable. It insures that at least one respectable professional other than those sitting on the hearing panel has reached similar conclusions and is willing to be held accountable for them not only by the accused's counsel but by the profession. It thus protects against an arbitrary, *ad hoc* determination to achieve extralegal agency objectives. *See Hurtado v. California*, 110 U.S. 516, 535 (1884) as to the meaning of "law" in "due process of law."

> Law is something more than mere will exerted as an act of power. It must not be a special rule for a particular person or a particular case, but in the language of Mr. Webster . . . 'the general law, a law which hears before it condemns, which proceeds upon inquiry, and renders judgment only after trial . . . excluding . . . special, partial, and arbitrary exertions of power under the forms of legislation.

See also Ohio Bell Telephone Co., supra, 301 U.S. at 304 (Cardozo, J.) ("All the more insistent is the need, when power has been bestowed so freely, that the 'inexorable safeguard' . . . of a fair and open hearing be maintained in its integrity.").

The agency's combination of functions – especially when exercised by part-time, unpaid members

of a profession, with one foot in government regulation and one foot in private practice, who will also often have strong professional views based not on hard evidence, but unacknowledged predispositions and self-interest – may be the most important reason that all states and the federal government require judicial review in cases like this. *See* RCW 34.05.570(3). Such review is impossible, as the courts rejecting *Jaffe* have indicated, if the reviewing court does not have an adequate record providing not only the specific conclusions that the expert is offering, but the background and context of the entire controversy that will be brought out by cross-examination, allowing the court to determine if the agency decision is at least plausible. *See Franz v. Board of Med. Qty. Assur.*, 31 Cal.3d 124, 139 (1982) ("the agency record must provide as complete a basis for judicial review as due diligence makes feasible . . . [and] include any technical matter necessary to enable a lay judge to determine whether the agency's decision has adequate support.").

The Order finds that the physician's device was inefficacious, because it assertedly diagnosed the patient with an egg allergy he did not have. App.55-56. No physician or anyone else testified to this. There were no medical records showing that the patient had ever been tested for food allergies. The Order was in effect diagnosing the patient's allergenic condition two and a half years before the hearing, without anyone examining him and/or testing him – even at the time of the hearing. If an expert – say, a

physician specializing in allergies – had been required to so testify, it is highly unlikely that any reputable one could be found; if found, highly unlikely that he could survive cross-examination. Indeed, to give such an opinion without an examination and testing would ordinarily be malpractice. *See Ancier v. State, Dept. of Health*, 140 Wash.App. 564, 571, 166 P.3d 829, 833 (Div. 1, 2007).

The underlying logic of the Board's decision was that because on this one occasion the physician had assertedly misdiagnosed an allergy, the device was inefficacious and the physician negligent. That the board could have found a physician to offer such opinions about efficacy and negligence based on one anecdote seems inconceivable, and yet it did so, because it obviously believed it had nothing else better to offer. The mere fact that a professional made an error of judgment – which is what a misdiagnosis is – is never by itself negligence or every professional (including every judge) would be guilty of unprofessional conduct over and over again. *See, e.g., Gerard v. Sacred Heart Medical Center,* 86 Wn.App. 387, 389, 937 P.2d 1104, 1105 (Div. 3, 1997) (error in judgment is not in itself negligence). *Webb v. Arizona Bd. of Med. Exmnrs.*, 202 Ariz. 555, 560, 48 P.3d 505, 510 (App.Div.1, 2002).

In any event, if such an expert had been identified, Petitioner would have been able to prepare a defense to such testimony, conducting more and different discovery, deposing the patient differently,

deposing the putative expert, and presenting his own independent expert to rebut it.

The evidence relied on by the Order – the Supreme Court and the Court of Appeals in a departure from fundamental administrative law principles relied on wholly different evidence – was primarily elicited by a panel member after the board's counsel had finished his examination of the patient. CR 2269; App.161-62. The patient had never been told he had a food allergy by anybody else, and he had no reaction to eggs of the type he had to pollen. This lay testimony was the support offered for the finding that he had no egg allergy two and a half years earlier. It is difficult to take this seriously and it is noteworthy that neither the Court of Appeals nor the Supreme Court attempted to rely on it. *See* App.1,9-10,15,24-30.

If this Court feels it has the time, it can by carefully comparing the two appellate decisions with the Order confirm that each tribunal came up with a different theory based on facts, findings and evidence it invented or distorted, critical parts of which were not only not in the Order, but actually contradicted it.

In addition, the Order itself found that the patient had significant symptoms, including severe fatigue, sluggishness, aches and pains, etc. App.51-52,¶1.13. Without expert testimony a reviewing court could not know whether these could be from a food allergy – as the physician in fact testified in passing and, as the Order itself implicitly acknowledges,

finding that he told the patient that blood tests showed food allergies that might be weakening him. App.320,52-53,¶1.15,1.16.

Similarly, the Order finds that the physician did not take the "necessary" safety precautions to ensure the device was safe. App.56,¶1.27. But there was no testimony – expert or otherwise – asserting or supporting this conclusion. No one testified that any precautions were necessary and what they would be if there were any. The Order acknowledges that the physician discussed the device with his colleagues and with the vendor (earlier in the Findings it acknowledges that his investigation was even more extensive than that; App.50-51; *see also* App.132-33,305-07,312,327,332-33,336).

He was never asked what the content of those discussions were and thus there was no basis for finding that they did not provide all of the information he needed (which no one had testified to). But be that as it may, no one – expert or lay person – testified that the device required an investigation more extensive than consultation with colleagues and a vendor. *See* App.43-47.

The Order's concern seems to be that the physician when asked about the device said that he did not know the physics behind it and was not sure anymore of the exact voltage. If this was necessary for him to know – do people who use electronic devices know the physics behind them and voltage they produce – no one so testified. The only possible basis for the view

was the unarticulated, untested assumption of the members on the hearing panel. Because there was no witness to testify to any of this, Petitioner could not prepare a defense against this extraordinary finding either. Again, on what basis can a reviewing court find that such a finding is not arbitrary and capricious or that it is based on substantial evidence?

The *Jaffe* doctrine leaves the reviewing courts at sea so that not feeling they can understand the technical facts in the record and not knowing which way to turn, they adopt what appears to be the safest course: accept the agency view and struggle to find a rationale that can justify it. The Washington Supreme Court's opinion, like that of the other two courts below, is a textbook example of this: it is riddled with key misstatements of fact, profoundly elementary errors of logic and is incoherent at the point where it purports to explain its decision.

Although Dr. Ames cannot pretend to understand the reasoning by which that court upheld the Order, it seems to think that its decision is adequately justified, because there was "some expert testimony . . . offered . . . and the board issued findings of fact based on" it. App.9. As we have seen, this assertion by the Court is simply false. Of course, the issue is not whether there "was *some* expert testimony" but whether the testimony went to the factual determination that required expert evidence. But the Order, and, specifically, the Analysis and paragraph 2.3 of the Order, make clear that the Order did not give the testimony that the Court discusses any

weight or relevance. *See* in addition, App.45-47 and ¶¶1.3 and 1.4 acknowledging that the board found that the device, although cleared for biofeedback, had been designed primarily for EDS and related acupuncture uses. App.49.

The two witnesses whom the court says the Order relies on were Petitioner's witness, Mr. Clark, its primary reliance, and Dr. Sherman. The reasons why the hearing panel did not rely on them would be obvious if the Court were as familiar with the record as it was with the board's briefing on appeal.

Mr. Clark testified that the device was designed for EDS and NAET (acupressure) muscle testing (applied kinesiology), the use that Dr. Ames made of it. CR 2875-76; App.285-87. He submitted it for biofeedback only to get it on the market, a procedure suggested by the FDA itself, and sanctioned by *Buckman* and 21 U.S.C. §396 as well as everyday practice. CR 2871; App.281-82. His statement that the device does not itself give a medical diagnosis or a cure is irrelevant, because Petitioner did not claim to and did not use it to do so. App.133-34,136-40,118,121-22,127-28. Nor did he purport to use it for biofeedback.

Dr. Sherman did not say, as the Court claimed, "that galvanic skin recorders *like LISTEN* do not have the ability to diagnose ailments or treat allergies": he specifically acknowledged that he had never seen anything like the device and the Commission

expressly found that he was not competent to testify about it. CR 2298-2299,1853; App.179-81,45-47.

Dr. Sherman did testify that he did not know of any biofeedback device that "can . . . *itself*, make a diagnosis." CR 2317; App.182-83. But the Order's findings themselves show more than once, even though the Washington Supreme Court appears wholly unaware of their content, that Petitioner did not use the device to itself provide him with a diagnosis; he used it in a muscle test to help him to do so, as part of a larger assessment and treatment process. CR 1856-58,¶¶1.7, 1.12, 1.16; App.50-53 ("The Respondent informed Patient One that the LISTEN device helped him make a diagnosis."). The board's counsel himself acknowledged that the physician's assessment involved using the device only as part of a muscle test, which itself was part of a larger protocol involving blood testing and history taking. CR 2542.

The court's logic was that if the device was a biofeedback device – because it had been submitted and approved as one – it could not be anything else as well. But that is not only an indefensible inference, it was contradicted by Mr. Clark who made it clear that his device did much more than biofeedback and by the Order itself. *See, e.g.*, App.49,¶¶1.3, 1.4. Moreover, Dr. Sherman never made a categorical statement that there was no device that could perform biofeedback and do other things as well. *See generally* CR 2316-19; App.181-186. Indeed, he acknowledged that a machine could contain both a biofeedback

capability and other capabilities, but if so, the latter would not be biofeedback. CR 2339,2345; App.195-96,196-197.

The evidence, such as it was, from Mr. Clark, that the device was submitted for biofeedback and that it does not give a medical diagnosis or cure allergies, and from Dr. Sherman that he knew of no biofeedback devices that did so, was wholly irrelevant, because it does not go to the efficacy of the LISTEN device for the purposes that Dr. Ames used it. *See* App.142. The argument underlying the Court's use of this testimony attacks a straw man. In fact, although it should not logically matter, Dr. Sherman specifically said that although they cannot themselves give a diagnosis, biofeedback devices are used to make diagnoses: they provide information on which such determinations are based. CR 2316-2317; App.181-82.

Notification of the Theory of Liability Only at the Time of Decision Is a Due Process Violation That Is So Obvious as to Raise Serious Issues About the Sensitivity to Due Process Values of the Courts Involved in This Case

The objection under the due process clause and Washington administrative law that there was inadequate notice of the facts that were found to establish liability was not even addressed by the Superior Court, although it was raised in the physician's Petition for Review and in his briefing to that court.

App.379,385,386. It was simply blown off by the Court of Appeals, which asserted without citation or elaboration that there had been adequate notice, without citation to the record, let alone demonstration by quoting any of this supposed language. App.26-27. It asserted falsely that the charges alleged that the patient was treated. But other than this assertion – which could so obviously be discredited by just looking at the charges and yet was made anyhow – it did not state where in the record these new allegations appear. *See* App.70-76.

It claimed there was a prehearing brief that informed Petitioner of the board's position, but it did not identify when it was filed and anything about what it *said*. *Ibid.* It did not address the fact that the board's prehearing statement says nothing about any of the new facts asserted to establish liability in the Order. App.99-100. There in fact was no such brief. As the Order itself recites, the board filed a post-hearing brief. App.42.

The Court of Appeals also made no attempt to explain why, even if such a brief had been filed at some time, such a filing would be adequate notice when the relevant regulations required that the charges contain a clear statement of the facts which the board had to prove to establish liability; the due process clause of the fourteenth amendment, as construed by Washington's Supreme Court, required that the charges be "clear and specific" so that the accused could "anticipate, prepare, and present a defense"; and the board had the power to issue an

amended statement of charges without leave at any time before the first day of hearing. WAC 246-11-250, 260, 520; App.416-18; *see In re Disciplinary Proceeding Against Romero*, 152 Wn.2d 124, 137, 94 P.3d 939, 945 (2004).

The issue was identified as one for which the physician sought review in his Petition to the Washington Supreme Court – and, indeed, was identified as one of three issues by the board's answer to his petition – and the Supreme Court granted review without limitation. App.12. Nevertheless, the Supreme Court when it issued its opinion stated that it had declined to review that issue. No order so stating has ever come to the attention of Petitioner.

The situation here is very like the one in *Ruffalo*, but there at least there was an amendment of the pleadings during the hearing. This court held that the charges that were filed against the attorney in that case became a trap when the testimony of the accused in support of his defense to those charges was then used to fashion a new charge during the hearing. *In re Ruffalo*, 390 U.S. 544, 551 (1968). In this case, the board filed charges for which it had no evidence and then conducted general discovery about the device and the patient during the hearing, basing its new theories of liability on the testimony elicited, but never amending the pleadings.

The case may be even more like *Nelson v. Adams USA, Inc.*, 529 U.S. 460, 466-469 (2000) where the principal of a defendant company was found liable

simultaneously with his addition to the case by amendment. Yet even in that case, the principal had had an opportunity to litigate the essential issues in defending his company and he knew before the court granted the motion to add him to the case and to the judgment that a motion was pending to do that. Here, the accused – in a quasi-criminal case – was first notified of the liability theories when he received the board's decision.

That this could be done – and be essentially ignored by three levels of state courts – should tell the court something about the sensitivity to due process issues that exists in too many state courts and why it may be time to issue a seminal opinion about the meaning of "meaningful notice," "meaningful hearing" and meaningful "judicial review."

CONCLUSION

If Petitioner has been able in the space available to make clear what happened below, that itself should demonstrate that the process given Petitioner below by the board and by Washington courts was not process of law and that the insensitivity to Rule-of-Law issues of the courts involved, as well as the many courts that still follow the *Jaffe* doctrine, compels this Court's attention. It cannot oversee state courts generally, but the events here show a pressing need today to elaborate, specify and clarify what due process means so that state legal systems do not

allow the Rule of Law to become a cliche with only a part of the meaning that it must have to insure some semblance of freedom in the administrative state.

This is a case about an unorthodox physician and an unorthodox device, and it should recall Justice Jackson's warnings against government-imposed orthodoxy. *See West Virginia State Board v. Barnette*, 319 U.S. 624 (1943). The contributions that the heretic, the maverick, the nonconformist make to society are always resisted by public opinion, established interests and special legislation, but they should not be further obstructed by courts that have lost sight of their highest duty – enforcing the Rule of Law. If this Court cannot police state administrative agencies and courts, it can at least provide another "fixed star in our constitutional constellation" to help guide them to their proper destination. *Id.* at 642.

Respectfully submitted this 17th day of December, 2009.

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Supreme Court of Washington,
En Banc.
Geoffrey S. AMES, M.D., Petitioner,
v.
WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMISSION, Respondent.
No. 80644-6.

Argued March 10, 2009.
Decided June 4, 2009.

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Michael K. McCormack, Attorney at Law, Maple Valley, WA, Amicus Curiae on behalf of Citizens for Health, American Association for Health Freedom and WA Choice.

OWENS, J.

¶ 1 Dr. Geoffrey Ames urges reversal of sanctions levied against him by the Washington State Health Department's Medical Quality Health Assurance Commission (MQAC) for violations of the medical professional misconduct statute, RCW 18.130.180. MQAC concluded after a hearing that Ames had engaged in unprofessional conduct in violation of

RCW 18.130.180(4) and had used an inefficacious device in contravention of RCW 18.130.180(16). Ames contends that no expert testified to the standard of care or that his device was inefficacious. Pet. for Review at 7-8. Ames now asks this court to hold that expert testimony regarding both elements was required and to reverse the lower court and remand to MQAC with instructions to dismiss and return Ames to the status quo ante. Suppl. Br. of Pet'r at 15, 19.

¶ 2 We affirm the Court of Appeals because expert testimony provided at Ames's disciplinary hearing constituted substantial evidence to support the decision of MQAC. The testimony of the maker of the device at issue, as well as an expert on such devices generally, offered on the record below was sufficient for the panel to find that Ames both fell below the standard of care and used an inefficacious device.

FACTS

¶ 3 The issues in this case arise out of Ames's treatment of Patient One (P1) for sluggishness and fatigue. Ames engaged in a purported holistic medical practice in Richland, Washington, combining traditional medical techniques with naturopathic and homeopathic medical techniques. During a visit, Ames discussed P1's symptoms and informed P1 that he may be suffering from allergies to eggs or mustard and that those allergies may be contributing to his symptoms. Ames proposed to use a device, the Life

Information System Tens (LISTEN), to test and treat P1 for his egg allergy.

¶ 4 LISTEN is a biofeedback machine – specifically, a galvanic skin response[1] machine – that measures changes in resistance, modeled in part on previous biofeedback machines developed for relaxation exercises. LISTEN has not been approved by the Food and Drug Administration (FDA) for use in detecting and/or treating allergies, although biofeedback machines have been approved for other uses. Ames had not been specifically trained to use LISTEN by the manufacturer, and he testified that he did not know the "physics" of the unit but understood in theory how the device should work. Clerk's Papers (CP) at 17. Ames learned to use LISTEN from other doctors who also use the device.

¶ 5 During P1's visit, Ames used LISTEN to attempt diagnosis of allergies. Ames instructed P1 to lie on his back while holding a small brass probe in his hand. The probe connected to LISTEN. While P1 lay prone, Ames performed a basic muscle resistance test by asking P1 to resist downward pressure on his upraised forearm, which P1 ably achieved. Next, Ames typed the word "eggs" into LISTEN's computer interface and performed the resistance test again. CP at 20. Apparently, Ames was able to force P1's arm

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[1] Galvanic skin response machines measure sweating from skin tissue, specifically to detect changes in sweat level in response to various stimuli. Administrative Record at 2318.

down. Finally, Ames placed a paper sheath over the sensor. When asked why he had done so by P1, Ames replied that he was able to replicate what the machine could do telepathically and that he could finish the treatment without the machine. CP at 21; Administrative Record (AR) at 2271-75(P1); *see also* AR at 2719-66 (similar testimony of Patient Three (P3)). At the conclusion of the visit, Ames instructed P1 to avoid eggs for 48 hours, else the treatment would not take.

051 Extra cent – Y found within cent – Y markup. 053 cent – Y cent – R found without first cent – Y.

¶ 6 After the visit, P1 complained to the Department of Health (Department) about Ames's method. P1 indicated that he was concerned about "Dr. Ames's views of mercury, lead poisoning, and chelation." *Ames v. Dep't of Health,* noted at 138 Wash.App. 1044, 2007 WL 1448758, at *2. "He also indicated concern with the doctor's obsession with alternative modalities." *Id.* Upon investigating P1's complaint, the Department filed a statement of charges against Ames. As a result of an administrative hearing on the matter, MQAC determined that Ames had committed acts of professional misconduct under RCW 18.130.180(4)[2]

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[2] "Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed." RCW 18.130.180(4).

and 18.130.180(16).[3] MQAC sanctioned Ames by suspending his license, a suspension that would be stayed provided that Ames complied with the administrative order. In its order, MQAC barred Ames from using LISTEN and ordered him to pay a fine.

¶ 7 MQAC is comprised of several members, including doctors, physician assistants, and public members who have no medical training. For a hearing, MQAC selects three members to adjudicate the matter. In the case of Ames, the panel consisted of one doctor, one physician's assistant, and one public member.

¶ 8 Ames petitioned for judicial review in the Benton County Superior Court, which affirmed his sanction. CP at 31-35. In an unpublished opinion, Division Three of the Court of Appeals affirmed. *Ames,* 138 Wash.App. 1044, 2007 WL 1448758. We granted Ames's petition for review. *Ames v. Dep't of Health,* 163 Wash.2d 1059, 187 P.3d 753 (2008).

SCOPE AND STANDARD OF REVIEW

¶ 9 We apply the standards of the Washington Administrative Procedure Act (WAPA), chapter 34.05 RCW, directly to the agency record in reviewing agency adjudicative proceedings. *William Dickson Co.*

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[3] "Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure, or service." RCW 18.130.180(16).

v. Puget Sound Air Pollution Control Agency, 81 Wash.App. 403, 407, 914 P.2d 750 (1996) (citing *Tapper v. Employment Sec. Dep't,* 122 Wash.2d 397, 402-03, 858 P.2d 494 (1993)). Under the WAPA, a reviewing court may reverse an administrative order (1) if it is based on an error of law, (2) if it is unsupported by substantial evidence, (3) if it is arbitrary or capricious, (4) if it violates the constitution, (5) if it is beyond statutory authority, or (6) when the agency employs improper procedure. RCW 34.05.570(3)(d), (e), (h), (i), (a), (b), (c); *Tapper,* 122 Wash.2d at 402, 858 P.2d 494; *Olmstead v. Dep't of Health,* 61 Wash.App. 888, 891-92, 812 P.2d 527 (1991).

¶ 10 When reviewing an administrative agency decision, we review issues of law de novo. *Kellum v. Dep't of Ret. Sys.,* 61 Wash.App. 288, 291, 810 P.2d 523 (1991) (citing *Franklin County Sheriff's Office v. Sellers,* 97 Wash.2d 317, 325, 646 P.2d 113 (1982)); *Haley v. Med. Disciplinary Bd.,* 117 Wash.2d 720, 728, 818 P.2d 1062 (1991). We can then substitute our judgment for that of the administrative body on legal issues. *Kellum,* 61 Wash.App. at 291, 810 P.2d 523; *William Dickson Co.,* 81 Wash.App. at 407, 914 P.2d 750. However, we accord substantial weight to the agency's interpretation of the law it administers – especially when the issue falls within the agency's expertise. *Haley,* 117 Wash.2d at 728, 818 P.2d 1062 (citing *St. Francis Extended Health Care v. Dep't of Soc. & Health Servs.,* 115 Wash.2d 690, 695, 801 P.2d 212 (1990)); *US W. Commc'ns, Inc. v. Utils. & Transp.*

Comm'n, 86 Wash.App. 719, 728, 937 P.2d 1326 (1997).

¶ 11 With regard to issues of fact, this court reviews the evidence submitted to determine whether it constituted substantial evidence to support the factual findings of the agency. RCW 34.05.570(3)(e). Substantial evidence is that which is sufficient "'to persuade a fair-minded person of the truth of the declared premises'." *Heinmiller v. Dep't of Health,* 127 Wash.2d 595, 607, 903 P.2d 433, 909 P.2d 1294 (1995) (internal quotation marks omitted) (quoting *Nghiem v. State,* 73 Wash.App. 405, 412, 869 P.2d 1086 (1994)). We have also held that medical review boards are able to rely on their own expertise in evaluating medical practices. *Wash. Med. Disciplinary Bd. v. Johnston,* 99 Wash.2d 466, 482, 663 P.2d 457 (1983); *Davidson v. Dep't of Licensing,* 33 Wash.App. 783, 785, 657 P.2d 810 (1983).

¶ 12 Dr. Ames petitioned for this court's review to consider the issue of whether expert testimony should have been offered on the standard of care with regard to Ames's techniques or on the efficacy (or lack thereof) of LISTEN.[4] We accepted his invitation originally to revisit our deferential rules with regard to MQAC's factual finding absent expert testimony. Generally, Washington law does not require that expert testimony be provided to MQAC, *see Johnston,* 99 Wash.2d

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[4] This court also declined review of the issue of proper notice raised by Dr. Ames.

at 482, 663 P.2d 457, and allows for the members to use their own expertise to evaluate various factual questions before them and to "draw inferences from the evidence presented to them." *Davidson,* 33 Wash.App. at 785, 657 P.2d 810. It is not inappropriate for MQAC to draw its own conclusions as to the acceptable standard of care. *See Johnston,* 99 Wash.2d at 482, 663 P.2d 457. As this court said in *Johnston,* "[a]s to such specialized matters, we give deference to administrative expertise." *Id.*

¶ 13 Ames claims that the hearing he received was fundamentally flawed because the Department failed to offer expert testimony on the issues of standard of care and device efficacy. While Ames acknowledges that this court evaluates MQAC's decision for substantial evidence, he argues that our standard of review loses its meaning when at least some of the evidence is present only in the minds of the experts on MQAC's panel. Ames further contends that our prior cases involving similar issues, *Johnston, Davidson, and In re Disciplinary Proceeding Against Brown,* 94 Wash.App. 7, 972 P.2d 101 (1999), do not stand for the proposition that MQAC can substitute its own impressions regarding the standard of care for evidence not submitted. He asks this court to side with the numerous state courts that have rejected such a notion when reviewing medical review board decisions.[5]

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[5] Pet. for Review at 13-14.

¶ 14 We decline his invitation because we do not agree that our substantial evidence standard is fatally flawed in the way Ames suggests. When some expert testimony has been offered to an adjudicative board, as in this case, and the board issued findings of facts based on the expert testimony, this court does not inquire whether the expert testimony fits within some preconceived formulation. But, cases in which the evidence is simply too bare to form a credibly persuasive argument in favor of the Department's factual allegations will be vacated under the substantial evidence standard. Thus, we will review the evidence on the record to determine whether a fair-minded person could have been persuaded of its truthfulness.

ANALYSIS

¶ 15 The expert testimony on the record supports the Department's position that MQAC was able to understand and resolve issues regarding the efficacy of LISTEN. James Clark, the creator of LISTEN, testified to the machine's uses and the capabilities for which the FDA had approved the machine. AR at 2870-71. Clark testified that the device was not submitted to the FDA for any diagnosis, treatment, or curing of allergies or any other ailments. AR at 2891-92. Another expert, Dr. Richard Sherman testified that galvanic skin recorders like LISTEN do not have the ability to diagnose ailments or treat allergies. AR at 2318-19. On cross-examination, Dr. Sherman confirmed that biofeedback devices are nothing more

than recorders and displayers of biofeedback. AR at 2326-31.

¶ 16 Despite such testimony, Ames testified that he used LISTEN to improve his assessment of his patients' potential allergies. AR at 2162. Further, he asserted that he understands the device to be able to detect allergies to certain foods. AR at 2160-61. Although he stated that LISTEN did not treat his patients' allergies, AR at 2163, his patients testified that they understood that LISTEN helped him diagnose, treat, and cure their allergies. AR at 2207-10, 2255-56 (testimony from P1); 2698-700 (testimony from Patient Two); 2745-47 (testimony from P3). Substantial evidence leads to the conclusion that Ames was using LISTEN for purposes for which the machine was not designed or approved. As such, no additional expert testimony was necessary to demonstrate the elements of professional misconduct alleged in the statement of charges.

¶ 17 During oral argument, Ames argued that significant debate exists about the efficacy of LISTEN for diagnosing and treating allergies. However, the only evidence on the record regarding such a debate consists of statements by Ames himself. MQAC is entitled to use its expertise to conclude that the testimony of Mr. Clark and Dr. Sherman outweighed any testimony of an alleged dispute in the medical community about the way in which Ames used LISTEN. We give deference to this use of MQAC's expertise and find that substantial evidence existed on the record to support its conclusion.

CONCLUSION

¶ 18 We hold that no additional expert testimony regarding LISTEN, or Ames's use of it, was necessary. The evidence presented demonstrated by clear and convincing evidence to a layperson that he was using a machine for purposes for which it was not designed and for which he was not specifically trained. Substantial evidence exists that he led patients to believe that LISTEN could diagnose and treat allergies, when in fact it could do neither, placing these patients at risk of harm. Therefore, we conclude that MQAC's findings were supported by substantial evidence and affirm its chosen sanctions. We affirm the Court of Appeals.

WE CONCUR: GERRY L. ALEXANDER, C.J., CHARLES W. JOHNSON, MARY E. FAIRHURST, BARBARA A. MADSEN, JAMES M. JOHNSON, RICHARD B. SANDERS, DEBRA L. STEPHENS and TOM CHAMBERS, JJ.

THE SUPREME COURT OF WASHINGTON

GEOFFREY S. AMES, M.D., Petitioner, v. WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMISSION, Respondent.	NO. 80644-6 **ORDER** (Filed Jul. 10, 2008) C/A NO. 24897-6-III

This matter came before the Court on its July 10, 2008, En Banc Conference. The Court considered the Petition and the files herein. A majority of the Court voted in favor of the following result:

Now, therefore, it is hereby

ORDERED:

That the Petition for Review is granted. The Petitioner's motion to strike is denied.

DATED at Olympia, Washington this 10th day of July, 2008.

For the Court

/s/ *Gerry L. Alexander*
CHIEF JUSTICE

THE SUPREME COURT
STATE OF WASHINGTON

[SEAL]

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Re: Supreme Court No. 80644-6 – Geoffrey S. Ames, M.D. v. Washington State Health Department Medical Quality Health Assurance Commission Court of Appeals No. 24897-6-III

Counsel:

In the above entitled cause, the following notation ruling was entered on March 4, 2009, by the Supreme Court Deputy Clerk:

PETITIONER'S OBJECTIONS TO SUPPLEMENTAL BRIEF OF RESPONDENT MQAC

"At the direction of the assignment justice, the Petitioner's Objections to Supplemental Brief of Respondent MQAC, which has been treated as a motion to strike portions of respondent's statement of facts, is denied."

Sincerely,

/s/ *Susan L. Carlson*
Susan L. Carlson
Supreme Court Deputy Clerk

SLC:alb

Court of Appeals of Washington,
Division 3.
Geoffrey S. AMES, Petitioner,
v.
WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMISSION, Respondent.
No. 24897-6-III.

May 17, 2007.
Reconsideration Denied Aug. 2, 2007.

Appeal from Benton Superior Court; Honorable Carrie L. Runge, J.

William Robert Bishin Esq., Law Offices of William R. Bishin PS, Seattle, WA, for Appellant.

S. Kim O'Neal, Attorney at Law, Olympia, WA, for Respondent.

UNPUBLISHED OPINION

KATO, J.*

The Washington State Department of Health, Medical Quality Assurance Commission (Commission), found Dr. Geoffrey Ames had committed unprofessional conduct by using an alternative medical device. The Commission determined his conduct fell below the standard of care and suspended his license for five years. But it stayed the suspension provided

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* Judge Kenneth H. Kato is serving as a judge pro tempore of the Court of Appeals pursuant to RCW 2.06.150.

that Dr. Ames comply with several conditions that included not using the device, paying a fine, and submitting his records for periodic evaluations. Dr. Ames appealed to superior court, which upheld the Commission's ruling. We affirm.

Dr. Ames, a licensed physician, is board certified in holistic medicine. In 1995, he began practicing in Richland, Washington, specializing in chronic fatigue and allergies. One of the methods used by Dr. Ames was acupressure.

Another method used by Dr. Ames employed a device called the Life Information System Tens device (LISTEN). It is a galvanic skin response machine that measures changes in resistance. James Clark developed it and submitted information to the Food and Drug Administration (FDA). LISTEN was described as having electrodermal screening techniques, alternative medicine techniques, and bioenergetics techniques. The FDA did not clear the device for these uses. Mr. Clark also developed other galvanic skin response devices that were cleared, but not approved, by the FDA.

Dr. Ames learned about LISTEN from colleagues. He understood the device functioned like a biofeedback machine. In 1997, he purchased it and learned how to operate it from colleagues. His nurse attended a course on the use of the device for electrodermal screening (EDS), but he did not find her training useful for his purposes. He used LISTEN when

treating his patients, but did not specifically bill them for it.

Dr. Ames saw Patient One on June 6, 2001, and July 10, 2001. The patient complained of fatigue, sluggishness, weak and tired joints and muscles, infrequent joint and muscle pain, and severe mood swings. During the first visit, Dr. Ames discussed metal toxicity, metal poisoning, and his alternative medicine practice. He ordered blood tests and a urine test.

On July 10, Dr. Ames reviewed the lab results with Patient One and told him he had a mineral imbalance, mineral deficiencies, and a low testosterone level. Dr. Ames thought Patient One might have some metal poisoning that contributed to his tiredness. He told him he should undergo treatment for metal poisoning and he might be allergic to eggs and mustard, allergies that could be weakening his body.

Dr. Ames then told Patient One about LISTEN and how it could be used to find out what was going on with his body. Dr. Ames said he would place a probe connected to LISTEN in the patient's hand. This would enable the doctor to make a diagnosis and possibly cure any allergies.

Prior to using LISTEN, Dr. Ames assessed Patient One's strength. While lying on his back, the patient raised his right arm and Dr. Ames asked him to resist while he tried to pull his arm down. This test revealed Patient One had a strong resistance. Dr.

Ames then had the patient raise his arm as before. The doctor typed the word "eggs" into LISTEN and asked the patient to resist when he pulled on his arm. Dr. Ames was able to easily pull the patient's arm down, indicating he had been compromised due to his egg allergy. Next, the doctor had Patient One roll over onto his stomach and he thumped his back with an acupressure device. Dr. Ames again did the resistance test with LISTEN, but this time he was not able to pull the patient's arm down. Dr. Ames told him his allergy was gone.

Dr. Ames advised Patient One not to eat any eggs for the next 24-48 hours or the treatment would not take. The patient believed any egg allergy he had was cured. He had never before been diagnosed as having an egg allergy. Dr. Ames told Patient One he would have to return to cure his other allergies because only one allergy at a time could be cured.

Dr. Ames disputed Patient One's account of the second visit, claiming he simulated the process he would use to treat the allergy through muscle testing but did not actually use LISTEN. He was merely informing Patient One about what might happen if he elected treatment.

Several weeks after his last visit, Patient One contacted the Department of Health (Department) because he was concerned about Dr. Ames's views of mercury, lead poisoning, and chelation. He also indicated concern with the doctor's obsession with alternative modalities.

After an investigation, the Department filed on July 10, 2002, a Statement of Charges against Dr. Ames, alleging he treated Patient One with LISTEN in violation of federal food and drug acts and state law. On February 5, 2003, the Department amended its charges against Dr. Ames to claim he was not acting within the required standard of care, his actions constituted moral turpitude, and he promoted an inefficacious device for personal gain. The Commission determined Dr. Ames violated (a) RCW 18.130.180(4) by being negligent in creating a risk the patient could be harmed and (b) RCW 18.130.180(16) by promoting an inefficacious device for personal gain. The Commission, however, did not find Dr. Ames had violated the standard of care or committed an act of moral turpitude. Based upon its findings, the Commission suspended his license. But the suspension was stayed provided Dr. Ames not use LISTEN in his practice, permit the Commission to conduct quarterly record reviews of his patients, submit a declaration he was complying with the order each quarter, and pay a $5,000 fine. Dr. Ames appealed this decision to the Benton County Superior Court, which upheld the Commission's ruling. This appeal follows.

The Department charged Dr. Ames with violating several provisions of the Uniform Disciplinary Act, chapter 18.130 RCW. This Act establishes the licensure and disciplinary procedure for health care professions. *Nguyen v. Dep't of Health, Med. Quality Assur. Comm'n,* 144 Wash.2d 516, 520, 29 P.3d 689

(2001), *cert. denied*, 535 U.S. 904, 122 S.Ct. 1203, 152 L.Ed.2d 141 (2002). RCW 18.130.100 provides that all disciplinary proceedings are governed by the Washington Adminstrative Procedure Act (WAPA), chapter 34.05 RCW.

"'In reviewing administrative action, this court sits in the same position as the superior court, applying the standards of the WAPA directly to the record before the agency.'" *Heinmiller v. Dep't of Health*, 127 Wn.2d 595, 601, 903 P.2d 433, 909 P.2d 1294 (1995) (quoting *Tapper v. Employment Sec. Dep't*, 122 Wash.2d 397, 402, 858 P.2d 494 (1993)), *cert. denied*, 518 U.S. 1006 (1996). Because this is a medical quasi-criminal proceeding, findings of fact must be proved by a clear preponderance of the evidence. *Nguyen*, 144 Wash.2d at 529, 534, 29 P.3d 689. Unchallenged findings are verities on appeal. *Haley v. Med. Disciplinary Bd.*, 117 Wash.2d 720, 728, 818 P.2d 1062 (1991). Conclusions of law are reviewed under the "error of law" standard. *Id.* In applying this standard, courts accord substantial weight to the agency's interpretation of the law, even though we may substitute our judgment for that of the agency. *Id.*

Dr. Ames claims the Commission erred by using its own expertise instead of taking expert testimony. But an administrative tribunal comprised of medical practitioners is competent to determine the propriety of medical conduct without expert testimony. *In re Discipline of Brown*, 94 Wash.App. 7, 14, 972 P.2d 101 (1998), *review denied*, 138 Wash.2d 1010, 989 P.2d 1136 (1999). Here, the Commission was comprised of

two medical professionals and an attorney. It heard testimony from Dr. Ames as well as another doctor. The Commission was not required to take any additional expert testimony. *Id.*; *see also* RCW 34.05.461(5).

The Department alleged Dr. Ames violated RCW 18.130.180(4). RCW 18.130.180 defines what acts constitute unprofessional conduct for a health care provider. Specifically, RCW 18.130.180(4) states "[i]ncompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed" constitutes unprofessional conduct. The section further states "[t]he use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed." *Id.* The Commission concluded the Department proved by clear, cogent, and convincing evidence that Dr. Ames had violated this section by using LISTEN with Patient One. The doctor assigns error to this conclusion of law, as well as several of the Commission's findings.

Dr. Ames assigns error to the first sentence of finding 1.7, which stated he did not know the physics behind the device or the voltage or amperage it used. In response to questions regarding the electricity sent to the body by LISTEN, Dr. Ames testified, "I believe the LISTEN device sends a current of five ohms, but I'm not the inventor of the machine, so I can't really give you a reliable answer on that." Board Record (BR) at 2097-98. He later testified, "I don't know the

physics behind it." BR at 2156. This finding is supported by clear and convincing evidence.

He also assigns error to the last two sentences of finding 1. 12, which indicate he used the device in assessing patients. Dr. Ames testified he used the device to help him assess the allergies of his patients and he did use it. He testified he used LISTEN on about 50 percent of his patients. The device helped him to speed up his assessment of patients. The finding is supported by clear and convincing evidence.

Dr. Ames also assigns error to a sentence in finding 1.13 indicating Patient One described his symptoms on the date of his initial visit; a sentence in finding 1.15 that he told Patient One eggs and mustard could be weakening his body; and a sentence in finding 1.16 stating he told Patient One he could cure his egg allergy. These findings, however, are all supported by the testimony of Patient One.

Dr. Ames assigns error to findings 1.17-1.23 to the extent an allergy other than hay fever was implied. These findings indicate Dr. Ames treated Patient One for an egg allergy. They are supported by the patient's testimony. The doctor also assigned error to the first sentence of finding 1.24, which states he told Patient One he could only treat one allergy at a time and the patient would have to come back for additional treatments to treat each allergy. Again, this finding is supported by the patient's testimony.

Dr. Ames further assigns error to findings 1.25-1.29, which state Dr. Ames used LISTEN to treat

Patient One for his allergy to eggs, but the device could not provide such treatment. The findings question the diagnosis of egg allergy and indicate Dr. Ames used the device for his own personal gain and failed to ensure it was not harmful to his patients. The findings indicated Dr. Ames's use of the device precluded him from making a proper diagnosis and treatment, thus subjecting Patient One to an unreasonable risk of harm. Patient One's testimony supports these findings with regard to his visits and treatment with Dr. Ames, who admitted using LISTEN with his patients and that it improved his efficiency in treating patients. Other patients testified as to what Dr. Ames told them about LISTEN and how he used it in their treatments. Dr. Ames testified it was possible to cure an allergy in one visit. From this testimony, the challenged findings were supported by clear and convincing evidence.[1]

Based on its findings, the Commission concluded Dr. Ames violated RCW 18.130.180(4). It believed the doctor violated this section because his actions created an unreasonable risk that Patient One could be harmed.

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[1] Whether LISTEN had FDA clearance or approval was argued by both parties. The Commission found the FDA had not cleared or approved the device. (findings 1.3-1.6, CP at 16-17). Dr. Ames did not challenge these findings and therefore they are verities. *Haley,* 117 Wash.2d at 728, 818 P.2d 1062. Furthermore, these findings were supported by the testimony of the device's creator and the FDA. In any event, FDA clearance, or lack of it, was not of great import in the Commission's ruling.

Dr. Ames contends the determination of negligence under this section was predicated on finding that LISTEN was an inefficacious device because it could not be used to make an appropriate diagnosis and/or provide effective treatment. The Commission, however, determined Dr. Ames used LISTEN to erroneously diagnosis and treat an egg allergy and consequently created an unreasonable risk Patient One would be harmed. Its conclusion was based on the following facts.

Dr. Ames testified about allergies and tests used to diagnose allergies. He testified kinesiology, the arm muscle testing process described by Patient One, can indicate an allergy. He also discussed blood tests and skin tests used by allergists. Dr. Ames did use a blood test, but did not do a skin test on Patient One. He used LISTEN to assist him in diagnosing allergies, but he did not have any evidence LISTEN was efficacious for diagnosing allergies. He had only heard from colleagues that a device similar to it was efficacious. Dr. Ames admitted he did not understand the physics behind the device and was unsure what voltage it produced. He did not receive any claims, warnings or labeling with the device. He received no personal training on LISTEN. Patient One testified that in his second visit, Dr. Ames used LISTEN to diagnose and treat an allergy to eggs. Based on these facts, the Commission did not err by concluding Dr. Ames created an unreasonable risk of harm to Patient One by using LISTEN to diagnose and treat allergies without any evidence the device was effective

for that purpose. Furthermore, he created an unreasonable risk of harm to Patient One by using LISTEN without understanding how it worked. Dr. Ames failed to establish he had any evidence from which he based his conclusion the device was appropriate to use in the diagnosis and treatment of allergies.

Dr. Ames claims this conclusion is flawed for two reasons. First, he asserts any error he made was a one-time error in judgment and did not constitute negligence. But the Commission was not asked to determine if the device was inefficacious for every possible use. The Statement of Charges indicated Dr. Ames's use of the device with Patient One constituted negligence. The charge and the underlying statute is specific to a patient. *See* RCW 18.130.180(4). The evidence clearly and cogently established Dr. Ames's use of the device with Patient One created an unreasonable risk of harm, thus establishing a violation of RCW 18.130.180(4). The Commission was not required to conclude the device was inefficacious in all circumstances.

Dr. Ames also claims the blood tests established Patient One had an egg allergy. Accordingly, the Commission erred by concluding Dr. Ames's treatment of Patient One for an egg allergy was based on LISTEN and by concluding Patient One did not have an egg allergy. There was evidence that Dr. Ames did a blood test on Patient One who testified Dr. Ames told him his blood test detected an allergy to eggs. But Dr. David Martin, Dr. Ames's own expert, testified that a blood test result alone was not a basis for treatment.

Patient One testified he did not like eggs, but he had no symptoms indicating an allergy to eggs and had never been diagnosed with an egg allergy prior to Dr. Ames's diagnosis.

The Commission's ruling, however, was not based on Dr. Ames's diagnosis that Patient One had an egg allergy. It found Dr. Ames created an unreasonable risk of harm to Patient One by using LISTEN to treat his egg allergy. This risk was amplified because Dr. Ames did not understand the mechanics behind the device. A blood test suggested the possibility of an egg allergy, but it did not change the fact that Dr. Ames treated this allergy with a device he did not understand and for which he had no training. This created an unreasonable risk of harm.

Dr. Ames further claims his supposed negligent use of LISTEN based on these facts was not charged and thus cannot support the Commission's conclusion. Specifically, he claims he was not prepared to defend against a claim that Patient One did not have an egg allergy. But the Statement of Charges clearly provides that his treatment of Patient One was at issue. It did not specifically charge him with misdiagnosing an egg allergy, but the Commission's decision was not based on a finding that Patient One had no egg allergy. The decision was based on the finding that Dr. Ames did not properly treat the allergy and used a device without proper investigation. The Statement of Charges put Dr. Ames on notice about his use of the device. The prehearing brief filed by the Department also put Dr. Ames on notice of its

position. In these circumstances, Dr. Ames cannot claim he was unaware of the facts used by the Department to support its charges.

He claims the conclusion of negligence based on a failure to investigate was also unsupported and improper because it was not charged. The charges against Dr. Ames involved improper use of LISTEN. Contrary to his assertion, the Department did argue that its case was based upon Dr. Ames's use of the device and that it was not proper in his medical practice. It was Dr. Ames's own testimony that provided support for the finding he did not understand the device, the physics behind it, or how it worked. His testimony also indicated he did not receive any training or literature on the device. The finding that Dr. Ames did not properly investigate LISTEN prior to using it on his own patients was supported by the record.

Dr. Ames argues that because he practices alternative medicine, the Commission impermissibly discriminated against him. He does not cite any supporting facts in the record. Moreover, nothing in the record suggests the Commission members were biased against Dr. Ames or alternative medicine.

A medical provider violates RCW 18.130.180(4) if he acts in a manner that creates an unreasonable risk of harm to a patient. Dr. Ames treated Patient One with LISTEN for an egg allergy. He knew very little about the device. The evidence was clear, cogent, and convincing that Dr. Ames's use of the device

created an unreasonable risk of harm. The Commission did not err.

Dr. Ames also claims the Commission erred by determining LISTEN was inefficacious and he promoted it for his own personal gain. RCW 18.130.180 states that it is unprofessional conduct for any licensed health care provider to promote for personal gain an unnecessary or inefficacious drug, device, treatment procedure, or service. The statute does not define "inefficacious." Webster's defines "inefficacious" as lacking the power to produce the desired effect. Webster's Third New World Dictionary, 1156 (1993). There was no evidence the device was capable of curing allergies. The findings support the conclusion that the device was inefficacious for this situation.

Dr. Ames appears to argue that in order for a device to be inefficacious, it must create an unreasonable risk of harm. He urges RCW 18.130.180(4) to be read in conjunction with RCW 18.130.180(16). An appellate court reviews questions of statutory construction de novo. *Ballard Square Condo. Owners Ass'n v. Dynasty Constr. Co.,* 158 Wash.2d 603, 612, 146 P.3d 914 (2006).

> The examination begins with the language of the statute and related statutes to determine whether plain statutory language shows the intended meaning of the statute in question. If this examination leads to a plain meaning, that is the end of the inquiry. If the statute is amenable to more than one reasonable

> interpretation, a court may then resort to legislative history, principles of statutory construction, and relevant case law to resolve the ambiguity and ascertain the meaning of the statute.

Id. (internal citations omitted).

RCW 18.130.180 begins by stating "[t]he following conduct, acts, or conditions, constitute unprofessional conduct for any license holder or applicant under the jurisdiction or chapter." The statute then lists 25 subsections that detail different conduct, acts, or conditions. Each numbered subsection is separate and distinct from the others and alone is unprofessional conduct. There is no basis for finding that portions or requirements of one subsection must be read into a different subsection. Thus, RCW 18.130.180(16) does not require that a device must demonstrate an unreasonable risk of harm in order to be inefficacious.

Dr. Ames further claims that even if the device was inefficacious, there was no evidence he used it to promote his own personal gain. The statute does not define "promote." "Promote" is defined as "to contribute to the growth, enlargement or prosperity of." Webster's Third New International Dictionary, 1815 (1993). The evidence established Dr. Ames used the device with about 50 percent of his patients. He stated his use of the device helped him speed up his assessment of patients. Three patients testified Dr. Ames used the device on them. All reported he told them the cure for their allergies was provided, or at

least substantially provided, by LISTEN. He also told them he could only cure one allergy at a time.

The Commission entered several findings detailing Dr. Ames's use of LISTEN in his practice. Those findings were supported by clear and convincing evidence. The findings in turn support the conclusion that Dr. Ames used the device to promote his own personal gain. The evidence also showed clearly and convincingly that the device was inefficacious and could not produce the desired effect. The Commission did not err by finding Dr. Ames had violated RCW 18.130.180(16).

Dr. Ames argues the sanctions imposed were a manifest abuse of discretion because the evidence did not support a finding that he violated RCW 18.130.180(4) and .180(16). RCW 18.130.160 authorizes the imposition of sanctions based upon findings of unprofessional conduct. The Commission's findings of unprofessional conduct were proper. The sanctions imposed were permitted by RCW 18.130.160.

Affirmed.

A majority of the panel has determined this opinion will not be printed in the Washington Appellate Reports, but it will be filed for public record pursuant to RCW 2.06.040.

WE CONCUR: SWEENEY, C.J., and KULIK, J.

COURT OF APPEALS, DIVISION THREE, STATE OF WASHINGTON

GEOFFREY S. AMES, M.D., **Petitioner,** **v.** **WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMISSION,** **Respondent.**	**No. 24897-6-III.** **ORDER DENYING MOTION FOR RE-CONSIDERATION; ORDER DENYING MOTION TO MODIFY CLERK'S RULING** (Filed Aug. 2, 2007)

THE COURT has considered petitioner's motion for reconsideration of this Court's decision of May 17, 2007, and the answer thereto, and is of the opinion the motion should be denied.

THE COURT has further considered the petitioner's objection to the Clerk's Letter of July 9, 2007, and is also of the opinion the objection should be denied. Therefore,

IT IS ORDERED, the motion for reconsideration of this court's decision of May 17, 2007 is hereby denied.

IT IS FURTHER ORDERED, the objection to the Clerk's Letter of July 9, 2007 is also denied.

DATED: August 2, 2007

FOR THE COURT: /s/ *Dennis J. Sweeney*
DENNIS J. SWEENEY
CHIEF JUDGE

Superior Court of the State of Washington
for Benton and Franklin Counties
7122 W. Okanogan Place, Box D
Kennewick, WA 99336

Judge
Carrie L. Runge

Benton County Justice Center
Franklin County Courthouse
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December 20, 2005

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Ms. Kim O'Neal
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Re: *Ames vs. Medical Quality Assurance Commission*
Benton County 04-2-01837-1

Dear Counsel:

As you know, this letter opinion was started before today; however, I lost the first document that I had saved to a disk.

In any event, this matter is before the court because Dr. Ames asserts that the Medical Quality Assurance Commission erred in entering certain findings of fact and conclusions of law. See Petitioner's Opening Brief at pages 3 and 4. The party challenging an administrative order bears the burden of establishing that

it is invalid under the Administrative Procedures Act. RCW 34.05.570(1)(a). In this case, Dr. Ames bears the burden of proof.

Because Dr. Ames asserts the invalidity of the Commission's order in an adjudicative proceeding, the applicable standards for granting relief are found in RCW 34.05.570(3). That subsection sets out nine standards for granting relief, of which Dr. Ames asserts the following three:

> (d) the agency has erroneously interpreted or applied the law;
>
> (e) the order is not supported by evidence that is substantial when viewed in light of the whole record before the court which includes the agency record for judicial review, supplemented by any additional evidence received by the court under this chapter; and
>
> (i) the order is arbitrary and capricious.

See RCW 34.05.570(3)(a)-(i). Dr. Ames challenges the Commission's order arguing that the Commission erroneously interpreted or applied the law, that the Commission's Final Order lacks substantial evidence in the record and is arbitrary and capricious.

This court is mindful that the standard of review for all of Dr. Ames' challenges accords substantial deference to the decision of the Commission.

I. Challenges to the Findings of Fact.

Dr. Ames assigns error to the following findings of fact: 1.12, 1.13, 1.15, 1.16, 1.17-1.22, 1.24, and 1.25-1.29.

The standard of review for factual determinations is the "substantial evidence" test. The substantial evidence test is highly deferential to the administrative fact finder, and the same deference is afforded to the Commission's factual findings as an appellate court would afford to a superior court's factual findings. *Motley-Motley, Inc. v. State*, 127 Wn. App. 62, 110 P.3d 812 (2005) *citing King County v. Central Puget Sound Growth Mgmt. Hearings Bd.*, 142 Wn.2d 543, 553, 14 P.3d 133 (2000). Substantial evidence is evidence sufficient to persuade a fair-minded person of the truth of the finding. *Heinmiller v. Dept. of Health,* 127 Wn.2d 595, 607, 903 P.2d 433 (1995).

From this court's perspective, 1.13, 1.16, 1.17-1.22, 1.24 and 1.25 are all findings of fact that are supported by the testimony of Patient One. The Commission found the testimony of Patient One more credible than Dr. Ames. The Commission was entitled to accept Patient One's testimony as to the conduct of Dr. Ames and was entitled to find Patient One's testimony more credible than that of Dr. Ames. *See Nghiem v. State,* 73 Wn. App. 405, 869 P.2d 1086 (1994). This court will not disturb those findings.

The substantial evidence test necessarily requires this court to view the evidence and the reasonable inferences from the evidence in the light most

favorable to the party who prevailed in the highest forum that exercised fact-finding authority. This is a process that necessarily entails acceptance of the fact finder's views regarding the credibility of witnesses and the weight to be given reasonable but competing inferences. *Heinmiller v. Dep't of Health*, 127 Wn.2d 595, 607, 903 P.2d 433 (1995) (quoting *Nghiem v. State*, 73 Wn. App. 405, 412, 869 P.2d 1086 (1994)). The Commission specifically found Patient One credible when he testified about his visits with and treatment by Dr. Ames. See page 4 of the Commission's Findings of Fact, Conclusions of Law and Final Order.

Dr. Ames argues that if he were a conventional physician, the Commission would have found in his favor regarding credibility determinations over that of Patient One. However, there is nothing in the record to suggest that the Commission was biased or prejudiced against Dr. Ames because he is an alternative physician. From this court's perspective, such argument is merely speculative on the part of Dr. Ames.

With regards to the remaining challenged findings of fact, 1.12, 1.15, and 1.26-1.29, the issue for the court is whether those findings are supported by substantial evidence in the record. As pointed out in the Respondent's brief, such findings are in fact supported in the record, primarily by the testimony of Dr. Ames. See the Respondent's Brief at pages 10-19 for citations to the record. This court finds that there is

substantial evidence to support the remaining challenged findings of fact.

Dr. Ames argues that the Commission failed to consider the RAST blood test result as clinical evidence that Patient One had food allergies, specifically an egg allergy. However, as pointed out by the Respondent, Dr. Ames own expert witness testified that the RAST blood test result was not evidence of anything or justification for any treatment, whether conventional or non-traditional. See AR at 2993.

II. Challenges to Legal Conclusions.

Dr. Ames makes several challenges to the Commission's legal findings. He challenges the conclusion that expert testimony was not necessary to support the Commission's findings of negligence. Additionally, Dr. Ames specifically challenges conclusions of law 2.3, 2.6 and 2.7.

First, Dr. Ames argues that the Commission's use of their expertise violates the Administrative Procedures Act. However, such argument ignores the explicit authorization in the APA for agencies to use their expertise, RCW 34.05.461(5).

As pointed out by the Respondent, the *Brown*, *Johnston* and *Davidson* cases are health disciplinary cases, just like the one before the court. Those cases explicitly support the use of the Commission members' expertise and state that separate expert testimony is not necessary. *Brown vs. Dental Board,*

94 Wn. App. 7, 972 P.2d 101 (1998); *Johnston v. Medical Board,* 99 Wn.2d 466, 663 P.2d 457 (1983); and *Davidson v. Department of Licensing,* 33 Wn.App. 783, 657 P.2d 810 (1983).

Additionally, Dr. Ames argues that the Commission's Final Order cites these cases because their decision lacks evidence in the record. The Commission's order recites that the panel members used their expertise to evaluate the evidence they heard. *Not that they took official notice of technical or scientific facts or information outside of the administrative record which would have required notice to Dr. Ames pursuant to RCW 34.05.452(5)(b).*

The Commission is entitled to use their professional expertise and experience to evaluate, assess, and draw inferences from the facts and evidence that are in the administrative record, This is what they did and what they are entitled to do.

Secondly, addressing Dr. Ames assigned error to specific conclusions of law, 2.3, 2,6 and 2.7. An agency's conclusion of law can be modified if "the agency has erroneously interpreted or applied the law." RCW 34.05.570(3)(d). Under this standard, the reviewing court again accords substantial weight to the agency's interpretation of the law, although the court may substitute its judgment for that of the agency." *Haley v. Medical Disciplinary Bd.,* 117 Wn.2d 720, 728, 818 P.2d 1062 (1991); see *St. Francis Extended Health Care v. Department of Social &*

Health Servs., 115 Wn.2d 690, 695, 801 P.2d 212 (1990).

After reviewing the entire record before the Commission, the court finds that the conclusions of law are supported by substantial evidence in the record.

Dr. Ames argues that the Commission cannot find a violation under RCW 18.130.180(16) if an unreasonable risk of harm has not been established under RCW 18.130.180(4). First of all, a plain reading of the statute does not support this argument. Additionally, this argument is completely without legal citation or authority. Therefore, the court rejects this argument.

III. The Arbitrary and Capricious Standard.

The arbitrary and capricious standard is similarly deferential to the Commission's decision. Action taken after giving a party ample opportunity to be heard, exercised honestly and upon due consideration, is not arbitrary or capricious. *Washington Medical Disciplinary Board v. Johnston,* 99 Wn. 2d 466, 483, 663 P.2d 457 (1983). Arbitrary and capricious action is "willful or unreasoning, without consideration and in disregard of facts or circumstances." Where there is room for two opinions, action is not arbitrary or capricious even though one may believe an erroneous conclusion has been reached. *Heinmiller v. Dept. of Health*, 127 Wn.2d 595, 609-610, citing *Pierce County Sheriff v. Civil Serv. Comm'n of Pierce County,* 98 Wn.2d 690, 695, 658 P.2d 648 (1983).

It is clear to this court that the action taken by the Commission was taken after giving Dr. Ames ample opportunity to be heard, was exercised honestly and upon due consideration. This is obvious to the court when reviewing the Final Order of the Commission. The Commission carefully considered the testimony of the witnesses, reviewed the appropriate law, considered the arguments of counsel, and upon reflection, dismissed two of the charges against Dr. Ames. This court does not find that Dr. Ames has met his burden of establishing that the Commission's action was arbitrary and capricious.

IV. Composition of Commission Panel.

Finally, Dr. Ames takes issue with the composition of the Commission panel arguing that having only one conventional medical doctor on the panel prejudiced the panel against him. There is no evidence in the record to support this argument. Nor is there any legal authority cited for the proposition that the commission panel should be composed of at least one physician that is an alternative care provider, as opposed to a conventional doctor. Given the lack of legal authority to support Dr. Ames position and given the lack of evidence to suggest that the commission panel was somehow prejudiced against Dr. Ames, the court rejects these arguments.

V. Sanction imposed by the Commission.

Dr. Ames challenges conclusion of law 2.7. COL 2.7 is the sanction imposed by the Commission as a result of finding that Dr. Ames committed unprofessional conduct pursuant to RCW 18.130.180(4) and (16).

This court is mindful that a challenge to the appropriateness of the sanction the Commission chose is subject to the highest standard of review, and its sanction decision is accorded the most deference of any administrative determination. This is so because the imposition of sanction is a matter uniquely within the Commission's expertise and discretion. An agency's determination of sanction is accorded considerable judicial deference because "it is peculiarly a matter of administrative competence." *Brown v. Department of Health, Dental, Disciplinary Bd.*, 94 Wn. App. 7, 972 P.2d 101 (1999).

This court cannot say that the sanction imposed against Dr. Ames is manifestly unreasonable.

For all of the above reasons, the court affirms the decision of the Medical Quality Assurance Commission.

Very truly yours,

/s/ *Carrie L. Runge*
Carrie L. Runge

cc: Superior Court File

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD FINDINGS OF FACT, CONCLUSIONS OF LAW AND FINAL ORDER

APPEARANCES:

Respondent, Geoffrey S. Ames, M.D.
William Bishin, Attorney at Law

Department of Health, by
The Office of Attorney General, per
Keith D. Armstrong, Assistant Attorney General

COMMISSION PANEL: Cabell Tennis, J.D., Public Member, Panel Chair
Jan Paxton, PA-C, Pro Tem
Sunanda Uberoi, M.D.

PRESIDING OFFICER: Arthur E. DeBusschere, Health Law Judge

The Medical Quality Assurance Commission (the Commission) convened a hearing on January 13-16, 2004 and February 10, 2004. The Department's post-hearing brief was submitted to the Commission on February 25, 2004. The Commission deliberated on March 10, 2004.

The Department of Health issued First Amended Statement of Charges alleging that the Respondent had violated the Uniform Disciplinary Act. License Suspended. Stayed.

ISSUES

Whether the Respondent engaged in unprofessional conduct within the meaning of RCW 18.130.180(1), (4), (7) and (16).

If the Department proves unprofessional conduct, what are the appropriate sanctions under RCW 18.130.160?

SUMMARY OF EVIDENCE

In consideration of this matter, the Commission heard over thirty-three hours of testimony and oral argument. The Department presented testimony of the following witnesses: Geoffrey Ames, M.D. (the Respondent); Patient One; Richard Sherman, Ph.D.; and Neil Ogden. The Respondent testified on his behalf and presented testimony of the following witnesses: Donald Volkman; Joan McVey; James Clark; and David Martin, M.D. The Department's had two exhibits admitted, which were numbered as Department's Exhibit No. 2 and Department's Exhibit No. 3. The Respondent had eight exhibits admitted, Respondent's Exhibits Nos. 1-8.

ANALYSIS

The Uniform, Disciplinary Act (the UDA) defines what conduct, acts, or conditions constitute unprofessional conduct. RCW 18.130.180. In this case, the Department alleged that the Respondent committed four violations under the UDA, specifically RCW 18.130.180(1), (4), (7) and (16).

First, the Department alleged the Respondent's conduct was unprofessional under RCW 18.130.180(1), unprofessional conduct is defined in part as:

> The commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person's profession, whether the act constitutes a crime or not.

RCW 18.130.180(1). During the hearing, the Commission granted the Respondent's motion to dismiss the alleged violation under RCW 18.130.180(1).

Second, the Department alleged the Respondent's conduct was unprofessional under RCW 18.130.180(4), which is defined as:

> Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed;

RCW 18.130.180(4).

Expert testimony is helpful, but not essential to the Department's case, nor would the lack of such testimony either support or require dismissal of the charges against Respondent. *Johnston v. Washington State Medical Disciplinary Board*, 99 Wn.2d 466, 663 P.2d 457 (1983); *Brown v. State Department of Health, Dental Disciplinary Board*, 94 Wn. App. 7, 972 P.2d 101 (1998). Based on the *Johnston* and *Brown* cases, the Commission can use its own expertise to evaluate the standard of care regarding the Respondent's actions with Patient One. No additional expert is necessary to resolve this case. RCW 34.05.461(5).

Third, the Department alleged the Respondent's conduct was unprofessional under RCW 18.130.180(7), which is defined as:

> Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice;

RCW 18.130.180(7). Specifically, the Department charged the Respondent for violating a federal code, 21 U.S.C. § 331(c), which provides as follows:

> Sec. 331. – Prohibited acts
>
> The following acts and the causing thereof are hereby prohibited:
>
> . . . .

> (c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

The Department also charged the Respondent for violating a state statute, RCW 69.04.040(1) and (3), which provides as follows:

> The following acts and the causing thereof are hereby prohibited:
>
> (1) The sale in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
>
> . . . .
>
> (3) The receipt in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the sale thereof in such commerce for pay or otherwise.

This statute is similar to the above federal code, 21 U.S.C. § 331(c). The facts that would apply to the federal code would apply as well to the allegations under RCW 69.04.040, regarding the LISTEN device being adulterated or misbranded.

In this case, Mr. Ogden did not know about the LISTEN device that was purchased by the Respondent. Likewise, Dr. Sherman not only did not know about the LISTEN device, but also had not seen or evaluated it. In addition, there was no evidence that the manufacturer or the Respondent made significant

changes to the LISTEN device that it thereby became adulterated. There was no evidence that the Respondent mislabeled the LISTEN device; thus, there was no evidence that it was misbranded. Finally, the Department failed to offer evidence that the Respondent delivered or offered it for delivery to someone else for pay. During the hearing, the Commission granted the Respondent's motion to dismiss the allegation of unprofessional conduct under RCW 18.130.180(7)

Fourth, the Department alleged the Respondent's conduct was unprofessional under RCW 18.130.180(16), which is defined as:

> Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure, or service;

RCW 18.130.180(16).

During the hearing, the Commission heard and observed the testimony of Patient One and the Respondent. The Commission finds Patient One credible when he testified about his visits with and treatment by the Respondent on June 6, 2001 and July 11, 2001. The Commission did not find the Respondent credible when he testified about his treatment of Patient One on these dates. RCW 34.05.461.

I. FINDINGS OF FACT

1.1 Geoffrey S. Ames, M.D., the Respondent, was issued by the state of Washington in December 1989, a license to practice as a physician and surgeon. The Respondent completed a pathology residency. He completed a year of internal medicine training. He started a family practice in Gardnerville, Nevada. The Respondent is board-certified in holistic medicine. The Respondent took an acupuncture course at UCLA, San Francisco. Since 1995, he has been practicing as a physician in Richland, Washington. The Respondent's practice includes the following specialties: NAET[1] allergy therapy, JMT allergy therapy, neuromodulation technique allergy therapy, acupuncture, acupressure and dermatology.

1.2 The Life Information System Tens device (the LISTEN device) is a galvanic skin response machine. The LISTEN device consists of a keyboard, monitor, a computer with hardware, foot mouse, black box used to create the circuit so an ohmmeter will work. The black box has a wire to a metal probe that is held by the patient in his/her hand. The LISTEN device is an electronic skin response device and it measures changes in resistance, which is the impediment of a flow of electrical current. The

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[1] NAET stands for Nambudripad Allergy Elimination Technique. Devi S. Nambudripad developed the NAET, which is a technique that treats allergies using acupressure.

LISTEN device uses low voltage, a current of five ohms, to measure galvanic skin resistance.

1.3 James Clark developed the LISTEN device. On January 7, 1992, he submitted information on a LISTEN device to the United States Food and Drug Administration (FDA). The LISTEN system was described as having electrodermal screening techniques, alternative medicine techniques and bioenergetic techniques. The device was not cleared with that labeling. It did not receive pre-market approval since it was not substantially equivalent to predicate devices studied by the FDA.

1.4 In August 1992, James Clark made a submission for the Digital Conductance Meter (DCM) to clear the ohmmeter and the capability for the Listen System without the acupuncture claims and to market the LISTEN device. The FDA cleared the DCM as a biofeedback device for relaxation training. The DCM had been submitted for other uses, but those were removed from the FDA file.

1.5 James Clark has a number of upgraded models that are galvanic skin response devices. They are called the Orion, the Pegasus and the Mira. These upgraded devices have the same hardware as the LISTEN device; they both have the ohmmeter, computer software and the signal generator. The only difference between the LISTEN device and the later devices was that the LISTEN device was a DOS-operated system while these upgraded devices were a WINDOWS based system.

1.6 In 1996, James Clark obtained clearance from the FDA for the Orion, the Pegasus and the Mira. In 1996, the FDA notified him that his devices (the Orion, the Pegasus and the Mira) were substantially equivalent to a predicate device, which permitted him to proceed to market the devices. James Clark received a pre-market "clearance," not a pre-market "approval." Nevertheless, he could not market the devices as being cleared, because the public might think that the FDA had approved them.

1.7 The Respondent does not know the physics behind the LISTEN device, nor did he know the voltage or amperage that the LISTEN device produces. The Respondent understands the LISTEN device functions like a biofeedback machine, but it is used in different ways. He used it in combination with kinesiology. Kinesiology is based on the theory that an imbalance in acupuncture meridians will make muscles weak. The Respondent learned kinesiology from a NAET course.

1.8 The Respondent heard about the LISTEN device from colleagues, from vendors and from attending conferences of the American Academy of Environmental Medicine. The Respondent has owned the LISTEN device since 1997, when he bought it from the company owned by James Clark. The LISTEN device was made in Utah.

1.9 The Respondent learned to operate the LISTEN device from his colleagues and from the manual, which told him how to operate it. The

manual did not make any claims on its use and provided basic instructions on how to turn it on and off. The LISTEN device had no labeling on it.

1.10 He also sent his office nurse to a course to learn about the LISTEN device. The nurse learned how to use it for Electrodermal Screening (EDS). On one hand, this was not helpful because he does not do EDS. On the other hand, it was helpful because it increased his understanding and knowledge about the device. The Respondent obtained information about the LISTEN device from others colleagues, including Dr. Nambudripad, who uses a machine similar to it, but who purchased it from a different manufacturer.

1.11 Before the Respondent purchased the LISTEN device, he talked with James Clark who informed him that it was registered with the FDA. The Respondent purchased a device that could be sold to him by the manufacturer. The Respondent purchased the LISTEN device in good faith.

1.12 Although the Respondent does not charge his patients specifically for its use, the Respondent bills his patients for visits that include the LISTEN device's use. The device helps in his assessment and speeds up his patient visits. When he sees a patient, the LISTEN device is part of the whole picture of assessment and treatment.

1.13 The Respondent saw Patient One on two occasions: June 6, 2001 and July 10, 2001. At the initial visit, Patient One informed the Respondent

that he had been tired. Just before the initial visit, Patient One filled out a health history provided by the Respondent. Patient One described the symptoms that he felt the day of the initial visit. Patient One felt fatigue and experienced sluggishness and that these symptoms were severe. Patient One frequently tired easily and felt weak. He experienced apathy and lethargy and the symptoms were severe.

1.14 At the initial visit, the Respondent discussed metal toxicity and metal poisoning with Patient One. The Respondent talked about his alternative medicine practice and informed Patient One that he would send him to the Tri-Cities laboratory for blood and urine testing. The Respondent took a hair sample. The first visit lasted about 30 to 45 minutes.

1.15 During the second visit on July 10, 2001, the Respondent reviewed Patient One's laboratory tests results. The Respondent reported to Patient One that he had a mineral imbalance, mineral deficiencies, and that his testosterone level should be higher. He reported that Patient One might have some metal poisoning which would contribute to the tiredness. He informed Patient One that he should undergo treatment for the metal poisoning. The Respondent also informed Patient One that foods like eggs and mustard could be weakening his body.

1.16 The Respondent informed Patient One that he had a machine that could be used to find out what was going on with his body. The machine that the

Respondent was referring to was the LISTEN device. The Respondent informed Patient One that he would place a probe in his hand and the probe was connected to the LISTEN device. The Respondent informed Patient One that the LISTEN device helped him make a diagnosis. The Respondent informed Patient One that he could cure the egg allergy and that eggs would not bother him again.

1.17 Before using the LISTEN device, the Respondent assessed the strength of Patient One's deltoid muscle to obtain a baseline. The Respondent had Patient One lie on his back. The Respondent put the probe in Patient One's right hand and raised Patient One's right arm to a 90 degree point from his body. Patient One had a ring on his left-hand and on his right wrist he wore a watch. The Respondent asked Patient One to resist as hard as he could while the Respondent tried to pull his arm down next to Patient One's body. During this test Patient One resisted pretty well and Patient One's resistance was strong.

1.18 The Respondent used the LISTEN device when he conducted the next muscle assessment. While Patient One was still lying on his back, the Respondent put the probe in Patient One's right hand and raised Patient One's right arm to a 90 degree point from his body. This time the Respondent had the LISTEN device operating and, using the keyboard, he typed in the word "eggs." The Respondent again asked Patient One to resist as hard as he could while the Respondent tried to pull Patient One's arm

down. This time the Respondent was then able to easily pull Patient One's arm down. When this occurred, the Respondent informed Patient One that he could pull his arm down, because his body had been compromised due to the egg allergy.

1.19 Next, for the treatment, the Respondent had Patient One roll over on his stomach and the Respondent thumped Patient One on his back with an acupressure device. The device had rubber tips on it like a plunger. While the Respondent thumped Patient One on his back, he mentioned acupressure.

1.20 After the acupressure treatment, the Respondent assessed whether it affected the muscles. The Respondent had Patient One roll over on his back again and the Respondent gave Patient One the probe that was connected to the LISTEN device. The Respondent had Patient One raise his arm to a 90 degree position and the procedure was repeated. The Respondent could not pull Patient One's arm down. The Respondent then said "See, it's gone."

1.21 After the Respondent used the LISTEN device, the Respondent performed an final assessment. The Respondent wrapped the probe in tissue paper and then had Patient One hold the probe with the tissue paper wrapped around it. Patient One asked him why he did this. The Respondent answered that he has done this so long, that he could do what the machine could do, and that he did not need the machine anymore.

1.22 After this series of assessments and treatment, the Respondent advised Patient One that he should not eat any eggs for 24 hours or perhaps 48 hours or the treatment would not take. Patient One understood that the Respondent had diagnosed that he was allergic to eggs, that the Respondent provided treatment, and that the Respondent cured him of his egg allergy. Patient One understood that he would be able to eat eggs and would have no allergic reaction.

1.23 In 1976-80, Patient One had been diagnosed by another health care practitioner that he was allergic to blowing dust and pollens for which Patient One took shots to help relieve the symptoms. He had also been diagnosed with hay fever, with resulting symptoms of respiratory difficulties, feeling plugged-up, sinus drainage, and itching of eyes.

1.24 At the end of the second visit, the Respondent informed Patient One that he could only treat one allergy at a time and that he would need to come in for additional visits to treat each allergy. The Respondent wrote out some prescriptions and suggested that the Respondent sign up for additional treatments. The Respondent prescribed testosterone, DHEA, multi-mineral vitamins and a low glycemic index diet to be followed by a Metabolic typing diet.

1.25 As a physician, the Respondent used the LISTEN device to treat Patient One for an egg allergy. The LISTEN device was inefficacious and did not cure an egg allergy. The LISTEN device did not provide any manner of treatment or assessment.

Before the Respondent's assessment and treatment for an egg allergy, Patient One had not been diagnosed to be allergic to eggs or mustard or any food allergies. There was no clinical evidence to support the Respondent's assessment and treatment that Patient One had an egg allergy. Before his visit with the Respondent, Patient One had not been advised that he was allergic to eggs and had no reaction to eating eggs, except that he does not like to eat them.

1.28 The Respondent promoted the use of the LISTEN device in his practice and for his own personal gain. He informed Patient One that he uses it for treatment. He billed Patient One for his treatment, which included using the LISTEN device. The Respondent was able to speed up his assessment and treatment by using it. He suggested to Patient One to return for additional treatments so he can treat each individual allergy.

1.27 As a physician, the Respondent failed to take the necessary safety measures to ensure that the LISTEN device would not be harmful to his patients. The Respondent obtained no literature or had no labeling on the LISTEN device, and he did not receive any personal training on its use. The Respondent only listened to his colleagues and to a salesperson. The Respondent did not know the voltage or amperage that the LISTEN device produces.

1.28 The Respondent's use of the LISTEN device, an inefficacious device, precluded him from

making as a physician an appropriate diagnosis and treatment. By using his credentials as physician, the Respondent took advantage of Patient One to use an inefficacious device to allegedly assess, treat and cure an egg allergy. By using the LISTEN device in his assessment and treatment of Patient One on July 10, 2001 for an egg allergy, the Respondent was negligent in his practice as a physician. The Respondent's use of the LISTEN device was not nontraditional treatment.

1.29 Making a false medical diagnosis through the use of an inefficacious device, providing an ineffective treatment, and misinforming Patient One that he had been cured, the Respondent subjected him to unreasonable risk of harm. The Respondent's reliance on the LISTEN device, an inefficacious device, created an unreasonable risk of harm to Patient One.

II. CONCLUSIONS OF LAW

2.1 The Commission has jurisdiction over the Respondent's license and over the subject matter of this proceeding. RCW 18.71; RCW 18.130.

2.2 The Washington Supreme Court has held that the standard of proof in disciplinary proceedings against physicians before the Washington State Medical Quality Assurance Commission is proof by clear and convincing evidence. *Nguyen v. Department of Health*, 144 Wn.2d 515, 534, *cert. denied*, 535 U.S. 904 (2002).

2.3 Based upon Findings of Fact, Paragraphs 1.1, 1.2 and Paragraphs 1.7 through 1.30 above, along with the above Analysis, the Commission concludes that the Department proved by clear and convincing evidence that Respondent violated RCW 18.130.180(4) and (16).

2.4 Based upon Findings of Fact, Paragraphs 1.1 through 1.6 above, along with the above Analysis, the Commission concludes that the Department failed to prove by clear and convincing evidence that Respondent violated RCW 18.130.180(7). This charge under RCW 18.130.180(7) shall be dismissed.

2.5 Based upon Findings of Fact, along with the above Analysis, the Commission concludes that the Department failed to prove by clear and convincing evidence that Respondent violated RCW 18.130.180(1). The Respondent purchased the LISTEN device in good faith. The decision to use an inefficacious device, even though its use resulted in unprofessional conduct, did not constitute an act of moral turpitude, dishonesty, or corruption. This charge under RCW 18.130.180(1) should be dismissed.

2.6 As a result of the unprofessional conduct found under RCW 18.130.180(4) and (16), the Commission may impose sanctions. The first consideration is the protection of the public. RCW 18.130.160.

2.7 Based upon the above Findings of Fact, Analysis and Conclusions of Law, the Commission concludes that the Respondent's license should be suspended, but the suspension should be stayed

provided that he complies with the conditions ordered below. The Respondent should not be permitted to use the LISTEN device with patients. The Respondent should pay a fine for his conduct and he should be monitored during this period of stayed suspension, including a regular review of his patient records. The Commission concludes that these conditions are necessary to ensure that sufficient safeguards are in place to protect the public.

III. ORDER

Based on the foregoing, the Commission hereby issues in this case the following ORDERS:

3.1 *Stayed Suspension*. The license to practice as a physician and surgeon in the state of Washington held by the Respondent, Geoffrey S. Ames, M.D., is SUSPENDED for a period of at least five (5) years from the date of service of this Order. The suspension of the Respondent's license is hereby STAYED, PROVIDED that the Respondent complies with the following terms and conditions in this Order.

3.2. *Limitation on Practice*. The Respondent shall not use the LISTEN device to assess for or to treat allergies. Further, the Respondent shall not have the LISTEN device in his medical office(s) where he sees and/or treats patients.

3.3 *Record Reviews*. Within thirty (30) days from the effective date of this Order, or as soon thereafter as deemed by the Commission or its

designee, the Department shall conduct a review of 10 to 15 patient records, randomly selected, on a quarterly basis. After a compliance hearing in review of this condition, the Commission at its discretion may order the record reviews to continue this quarterly review of the Respondent's records for an additional period as long as the Commission deems it necessary.

3.4 *Quarterly Declaration.* The Respondent shall submit a quarterly declaration under penalty of perjury stating whether there has been compliance with all conditions of the Order. The quarterly declarations shall be submitted to the Commission on the first day of the following months: September, December, March and June, unless ordered otherwise by the Commission.

3.5 *Compliance with Laws and Rules.* The Respondent shall obey all federal, state, and local laws and all rules governing the practice of medicine and surgery in the state of Washington.

3.6 *Fine.* The Respondent shall pay an administrative fine to the Commission in the amount of $5,000 (five thousand dollars) within 180 days of the entry of the effective date of this Order. The payment shall be made payable to the Washington State Treasurer and sent to the following address:

Medical Quality Assurance Commission
P.O. Box 1099
Olympia, WA 98507-1099

3.7 *Appearance at Compliance Hearings.* The Respondent shall appear before the Commission six months from the effective date of this Order, or as soon thereafter as the Commission's schedule permits, and shall present proof that he is complying with this Order. He shall continue to make such compliance appearances every six months, or as frequently as the Commission otherwise requires, until the period of stayed suspension, is terminated by the Commission. The Respondent shall be given notice of the compliance hearing, and if he fails to comply with this Order, the Commission may impose other sanctions as appropriate under RCW 18.130.160 to protect the public. Further, after a compliance hearing, the Commission may determine that the Respondent is in compliance and that he need not personally appear for a six-month compliance hearing.

3.8 *Costs.* The Respondent shall be responsible and shall pay for any and all costs involved in his compliance with any and all conditions in this Order.

3.9 *Responsibility for Providing Current Address.* The Respondent shall ensure that the Commission has his current practice and residence addresses and telephone numbers. The Respondent shall notify the Commission in writing of any address change within twenty (20) days after the change.

3.10 *Placed on Notice.* The Respondent is hereby placed on notice that it is his responsibility to ensure that all required reports are submitted to the

Commission on time and in the manner specified in this Order.

3.11 *Periods of Out of State Practice.* In the event the Respondent should leave Washington State to practice or reside outside the state, the Respondent shall notify the Commission, in writing, of the date of departure and return. Periods of residency or practice outside Washington State will not apply to the reduction of this five (5) year period of suspension.

3.12 *Modification of Order.* Except as provided above, the Respondent may petition the Commission for modification of this Order no sooner than five (5) years from the date this Order is signed. Upon notice duly given by the Commission, the Respondent shall appear personally before the Commission to present evidence in support of the petition. Evidence in opposition to the petition may also be presented for the Commission's consideration. The Commission has sole discretion to grant or deny the Respondent's petition for modification and has the authority to impose restrictions and/or conditions on the Respondent's license to practice as long as the Commission's jurisdiction over the Respondent, pursuant to this Order, continues.

3.13 *Termination of this Order.* After the Respondent completes the conditions of the stayed suspension and after five (5) years from the effective date of this Order, the Respondent may file a petition for termination of the stayed suspension and for a license to practice medicine and surgery in the state

of Washington without restrictions and conditions. At a hearing on the petition, the Department may present evidence in opposition to be considered by the Commission. After considering the petition and the evidence presented, the Commission has the sole discretion to grant or deny the Respondent's petition and has the authority to remove or to impose restrictions and/or conditions on the Respondent's license to practice as long as the jurisdiction remains over the Respondent, pursuant to this Order.

3.14 *Violation of Order.* If the Respondent violates any provision of this order, the Commission, after giving the Respondent notice and the opportunity to be heard, may set aside the stay order and impose the suspension, or may impose any sanction as it finds appropriate under RCW 18.130.160, or may take emergency action ordering summary suspension restriction or limitation of the Respondent's practice as authorized by RCW 18.130.150.

3.15 The charges in this matter that the Respondent's conduct violated RCW 18.130.180(1) and (7) are DISMISSED.

Dated this 30th day of May, 2004.

Medical Quality Assurance Commission

/s/ *Cabell Tennis*
CABELL TENNIS, J.D.
Panel Chair

FOR INTERNAL USE ONLY:
(Internal tracking numbers)
Program No. 2001-08-0007

CLERK'S SUMMARY

Charges	***Action***
RCW 18.130.180(1)	Dismissed
RCW 18.130.180(4)	Violated
RCW 18.130.180(7)	Dismissed
RCW 18.130.180(16)	Violated

THE SUPREME COURT OF WASHINGTON

GEOFFREY S. AMES, M.D., Petitioner, v. WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMISSION, Respondent.	**ORDER DENYING MOTION FOR RECONSIDERATION** (Filed Sep. 18, 2009) NO. 80644-6 C/A No. 24897-6-III Benton County Superior Court No. 04-2-01837-1

The Court having considered the Motion for Reconsideration;

Now, therefore, it is hereby

ORDERED:

That Petitioner's Motion for Reconsideration is denied.

DATED at Olympia, Washington this 18th day of September, 2009.

For the Court

/s/ *Gerry L. Alexander*
CHIEF JUSTICE

166 Wn.2d 255

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice As a Physician and Surgeon of: GEOFFREY S. AMES, M.D. License No. MD00026961	**Docket No. 02-06-A-1012MD** STATEMENT OF CHARGES (Filed Jul. 10, 2002)

The Program Manager of the Medical Quality Assurance Commission, (Commission), on designation by the Commission, makes the allegations below, which are supported by evidence contained in program case file 2001-08-0007MD. Any patients referred to in this Statement of Charges are identified in an attached Confidential Schedule.

Section 1: ALLEGED FACTS

1.1 Geoffrey S. Ames, MD, Respondent, was issued a license to practice as a physician by the state of Washington in December 1989.

1.2 On or about July 10, 2001, Respondent tested Patient One for food allergies using an electro-diagnostic device called the Life information System Ten device (LISTEN device). Respondent later admitted to the Department of Health representative that he uses the LISTEN device to detect food allergies in patients.

1.3 The LISTEN device uses low voltage to measure galvanic skin resistance.

1.4 The LISTEN device is a medical device under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h). A medical device may not be marketed until there is either an approved application for premarket approval, pursuant to 21 U.S.C. § 360e, or an approved application for an investigational device exemption, pursuant to 21 U.S.C. § 360j(g). There is no approved application for premarket approval or investigational device exemption for the LISTEN device.

1.5 A manufacturer is exempt from the requirements in the above paragraph if it files a pre-market notification under section 21 U.S.C. § 360(k), and the Food and Drug Administration (FDA) rules the device is "substantially equivalent" to a device already on the market. This is known as receiving "510(k) approval."

1.6 In 1996, the FDA granted "510(k) approval" for the Digital Conductance Meter to be used for relaxation training in the biofeedback process.

1.7 The FDA has not granted "510(k) approval" for the LISTEN device.

1.8 Although a component of the LISTEN device is a digital conductance meter, the LISTEN is different in several significant respects, including using different software, and is, therefore, a new

device, which must meet the requirements listed in paragraph 1.4, above.

1.9 Commercial distribution of a device prior to obtaining an approved application for premarket approval or an investigational device exemption, or receiving "510(k) approval" results in the device being adulterated under 21 U.S.C. § 351(f)(1)(B).

1.10 By receiving an adulterated device in interstate commerce, Respondent has violated 21 U.S.C. § 331(c).

1.11 Even if the "510(k) approval" for the digital conductance meter applied to the LISTEN device, Respondent did not use the digital conductance meter for its approved purpose.

1.12 The LISTEN device is a medical device under RCW 69.04.010. The use of an adulterated or misbranded device is prohibited under RCW 69.04.040(1) and (3).

Section 2: ALLEGED VIOLATIONS

2.1 The violations alleged in this section constitute grounds for disciplinary action, pursuant to RCW 18.130.180 and the imposition of sanctions under 18.130.160.

2.2 The facts alleged in paragraphs 1.2 through 1.12 constitute unprofessional conduct in violation of RCW 18.130.180(7), which provides in part:

(7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice.

Section 3: NOTICE TO RESPONDENT

The charges in this document affect the public health, safety and welfare. The Program Manager of the Commission directs that a notice be issued and served on Respondent as provided by law, giving Respondent the opportunity to defend against these charges. If Respondent fails to defend against these charges, Respondent shall be subject to discipline, pursuant to RCW 18:130.180 and the imposition of sanctions under 18.130.160.

DATED this 9th day of July, 2002.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY
ASSURANCE COMMISSION

/s/ *Lisa Pigett*
~~Maryella E. Jasson~~ Lisa Pigett
Disciplinary Manager

/s/ *Jim McLaughlin*
Jim McLaughlin
WSBA #27349
Assistant Attorney General
Prosecutor

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice As a Physician and Surgeon of: GEOFFREY S. AMES, MD License No. MD00026961 Respondent.	**Docket No. 02-06-A-1012MD** FIRST AMENDED STATEMENT OF CHARGES (Filed Feb. 5, 2003)

The Program Manager of the Medical Quality Assurance Commission, (Commission), on designation by the Commission, makes the allegations below, which are supported by evidence contained in program case file 2001-08-0007MD. Any patients referred to in this First Amended Statement of Charges are identified in an attached Confidential Schedule.

Section 1: ALLEGED FACTS

1.1 Geoffrey S. Ames, MD, Respondent, was issued a license to practice as a physician by the state of Washington in December 1989.

1.2 On or about July 10, 2001, Respondent tested Patient One for food allergies using an electro-diagnostic device called the Life Information System Ten device (LISTEN device). Respondent later admitted to a Department of Health representative that he uses the LISTEN device to detect food allergies in patients.

1.3 The LISTEN device uses low voltage to measure galvanic skin resistance.

1.4 The LISTEN device is a medical device under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(h). A medical device may not be marketed until there is either an approved application for premarket approval, pursuant to 21 U.S.C. § 360e, or an approved application for an investigational device exemption, pursuant to 21 U.S.C. § 360j(g). There is no approved application for premarket approval or investigational device exemption for the LISTEN device.

1.5 A manufacturer is exempt from the requirements in the above paragraph if it files a pre-market notification under section 21 U.S.C. § 360(k), and the Food and Drug Administration (FDA) rules the device is "substantially equivalent" to a device already on the market. This is known as receiving "510(k) approval."

1.6 In 1996, the FDA granted "510(k) approval" for the Digital Conductance Meter to be used for relaxation training in the biofeedback process.

1.7 The FDA has not granted "510(k) approval" for the LISTEN device.

1.8 Although a component of the LISTEN device is a digital conductance meter, the LISTEN is different in several significant respects, including using different software, and is, therefore, a new

device, which must meet the requirements listed in paragraph 1.4, above.

1.9 Commercial distribution of a device prior to obtaining an approved application for premarket approval or an investigational device exemption, or receiving "510(k) approval" results in the device being adulterated under 21 U.S.C. § 351(f)(1)(B).

1.10 By receiving an adulterated device in interstate commerce, Respondent has violated 21 U.S.C. § 331(c).

1.11 Even if the "510(k) approval" for the digital conductance meter applied to the LISTEN device, Respondent did not use the digital conductance meter for its approved purpose.

1.12 The LISTEN device is a medical device under RCW 69.04.010. The use of an adulterated or misbranded device is prohibited under RCW 69.04.040(1) and (3).

1.13 On or about June 6, 2001, Respondent saw Patient One complaining of chronic fatigue. Respondent ordered urine and blood tests and hair analysis.

1.14 On or about July 10, 2001, Patient One returned to see Respondent to discuss the test results. Respondent told Patient One that the blood tests showed a number of food allergies. Respondent then used the LISTEN device on Patient One. Respondent had Patient One lie down on a table and hold his left arm straight up in the air. Respondent

then asked Patient one to try to resist when Respondent attempted to push his arm down. Respondent pushed on Patient One's arm but did not push it down. Respondent then had Patient One hold a brass rod in his hand, which was connected to the LISTEN device, and typed in "eggs" into the device. Respondent asked Patient One to hold his left arm up in the air and to try to resist when Respondent attempted to push his arm down. Respondent then pushed Patient One's arm down and told Patient One that this showed he was allergic to eggs. Respondent repeated the test, but placed a piece of paper over the brass rod. When Patient One asked Respondent why he placed a piece of paper over the brass rod, Respondent told him he could emit the EMF frequency for eggs and many other foods through telepathy, so he hardly needed the device anymore.

Section 2: ALLEGED VIOLATIONS

2.1 The violations alleged in this section constitute grounds for disciplinary action, pursuant to RCW 18.130.180 and the imposition of sanctions under 18.130.160.

2.2 The facts alleged in paragraphs 1.2 through 1.14 constitute unprofessional conduct in violation of RCW 18.130.180(7), and (16) which provides in part:

> (1) The commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person's

profession, whether the act constitutes a crime or not.

(4) Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed.

(7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice.

The statutes Respondent violated are 21 U.S.C. § 331(c) and RCW 69.04.040(1) and (3), which provide as follows:

> Sec. 331. – Prohibited acts
>
> The following acts and the causing thereof are prohibited:
>
> . . .
>
> (c) The recipient in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

RCW 69.04.040 Prohibited acts:

The following acts and the causing thereof are hereby prohibited:

(1) The sale in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(2) The adulteration or misbranding of any food, drug, device, or cosmetic in intrastate commerce.

(3) The receipt in intrastate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the sale thereof in such commerce for pay or otherwise.

(16) Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure or service.

Section 3: NOTICE TO RESPONDENT

The charges in this document affect the public health, safety and welfare. The Program Manager of the Commission directs that a notice be issued and served on Respondent as provided by law, giving Respondent the opportunity to defend against these charges. If Respondent fails to defend against these charges, Respondent shall be subject to discipline, pursuant to RCW 18.130.180 and the imposition of sanctions under 18.130.160.

DATED this 5th day of February, 2003.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY
ASSURANCE COMMISSION

/s/ *Beverly A. Teeter*,
Health Administrator for
Lisa Noonan
Disciplinary Manager

/s/ *Keith D. Armstrong*
Keith Armstrong
WSBA #23795
Assistant Attorney General
Prosecutor

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice As a Physician and Surgeon of GEOFFREY S. AMES, M.D. License No. MD00026961 Respondent.	)	Docket No. 02-06-A-1012MD **ANSWER TO FIRST AMENDED STATEMENT OF CHARGES** (Filed Mar. 13, 2003)

Respondent Geoffrey S. Ames, M.D. defends against and answers the First Amended Statement of Charges filed by the Program Manager of the Medical Quality Assurance Commission as follows.

I. GENERAL COMMENTS

This Answer is based on investigation and legal analysis that has not been completed and Respondent reserves the right to take positions different from those set forth below should subsequent research and investigation suggest that he should do so.

On the basis of the investigation, research and analysis conducted and performed to this date, Respondent respectfully objects to the First Amended Statement of Charges – as he has objected to the original statement of charges – and the investigation and legal analysis on which it is based. Based on investigation and legal analysis undertaken for

Respondent to date, Respondent believes that he has reasonable grounds to contend that:

a) the factual investigation on which the First Amended Statement of Charges is based appears to be incomplete and flawed: an investigation which met minimal standards would have revealed that the central factual assertions that appear in the First Amended Statement of Charges are false;

b) the legal position taken by the First Amended Statement of Charges cannot be defended by reference to the federal and state statutes to which it refers and the reading of statutes on which the Statement principally relies so exceeds the bounds of reasonable interpretation that it raises serious issues about the motivations behind the First Amended Statement of Charges.

Unless settlement discussions or discovery unearth some reasonable basis for these erroneous statements of fact and law, Respondent will seek such redress as is available for the time, effort and expense that issuance of this First Amended Statement of Charges and the original statement of charges has caused and will cause him.

II. RESPONSES TO THE ALLEGATIONS OF THE STATEMENT

In response to the specific allegations of the Statement of Charges, Respondent admits, denies and alleges as follows:

ALLEGATION	RESPONSE
1.1	Does not contest.
1.2	Denies in its entirety, except that Respondent recalls telling an investigator that the LISTEN instrument played a role in the assessment of some patients with complaints or symptoms suggesting food allergies.
1.3	Denies for lack of knowledge.
1.4	Alleges that the LISTEN instrument may or may not be a medical device, depending on its use, and otherwise denies the factual statements in this Allegation either because they are false or because they are statements of law, not fact, and subject to legal argument.
1.5	Denies the statements of law, because they are not allegations of fact, and denies the statements of fact for lack of knowledge and for vagueness.
1.6	Alleges that the Digital Conductance Meter was cleared for marketing in interstate commerce by the FDA, which granted the manufacturer the right to market it in any of its various forms and configurations and denies the remainder of this Allegation

	because of the uncertainty of its terms of reference.
1.7	Denies.
1.8	Denies.
1.9	Denies.
1.10	Respondent did not receive an adulterated device in interstate commerce and he has not violated any statute, state or federal.
1.11	Denies.
1.12	Denies.
1.13	Denies in part because the statements are not true and in part for lack of knowledge and pending discovery, but admits that in the general time frame, Respondent did see patient A and did order tests for him in connection with complaints that he reported.
1.14	Denies in part because some of the statements are incorrect in themselves or in context and in part for lack of knowledge and pending discovery.
2.1	Denies.
2.2	Denies.

Respondent on information and belief alleges that the First Amended Statement of Charges and this proceeding is unconstitutional under the due process, equal protection, and supremacy clauses and the free expression and privacy protections of the United States and Washington constitutions, is arbitrary and capricious, is brought in bad faith and is unlawful under the Administrative Procedure Act.

Respondent requests that the Commission dismiss the First Amended Statement of Charges without further unjustified expense to himself, to the medical profession and to the public.

In the event that it elects not to do so, Respondent requests a settlement conference and, failing an outcome that he deems satisfactory, a hearing after all discovery of the facts alleged in the First Amended Statement of Charges.

DEMAND FOR UNBIASED HEARING PANEL

In addition, if this matter goes to hearing, Respondent demands a hearing panel in which a majority of the voting members consists of physicians who are expert in the fields of holistic, environmental, complementary, alternative, acupuncture and acupressure and/or natural medicine.

DATED: March 11, 2003

LAW OFFICES OF
WILLIAM R. BISHIN, INC., P.S.

By /s/ *William R. Bishin*
William R. Bishin
WSBA No. 8386
Roanoke Park Office
1404 East Lynn
Seattle, WA 98112
(206) 682-1584

Attorneys for Respondent
Geoffrey S. Ames

CERTIFICATE OF SERVICE

The undersigned declares under the penalties of perjury that he served the within Answer to First Amended Statement of Charges on March 11, 2003 by depositing in the United States mail postage pre-paid first class a copy thereof and addressed as follows:

Adjudicative Clerk's Office
1107 Eastside Street
P.O. Box 47879
Olympia, WA 98504-7879

Keith D. Armstrong, Esq.
Assistant Attorney General
6th Floor, Highways-Licenses Bldg
P.O. Box 40100
Olympia, WA 98504-0100

/s/ *William R. Bishin*
William R. Bishin
WSBA No. 8386

REPLY TO RECONSIDER ORDER GRANTING REQUEST FOR EXTENSION OF TIME TO ANSWER CHARGES

* * * *

February 19, 2003, the Department received notice that Dr. Ames filed notices to depose Dr. Randi Leggett and James Rich, PA-C, on March 13, 2003. Also on February 19, 2003, the Department received notice that Dr. Ames extension request was approved. See Order Granting Request for Extension. When the Department received Respondent's motions and notices, the Department's counsel was preparing for imminent hearings for the Dental Commission and the Pharmacy Board. On February 26, 2003, the Department filed its opposition to the Order Granting Extension of time and the deposition notices.

All Available Information Provided in Investigative File

Contrary to most states, Washington's disciplinary regulations provide that the entire investigative file be provided upon request to respondents after he or she has been charged with misconduct. The procedural rules allow for additional discovery and Dr. Ames went through the available methods to send interrogatories. WAC 246-11-370. Even though the interrogatory answers are duplicative of the information within the investigative file, the Department complied with the request. WAC 246-11-370(1)(a). Additionally, Dr. Ames filed requests for production. That request

was fulfilled even though it also duplicates information in the investigative file. In fact, all of the discovery requests made to the Department were fulfilled by January 17, 2003. The Department had no way of knowing if further discovery was pending. Prior to January 2003, the Department did receive notice of conceivable discovery, but no notice that further discovery was forthcoming. It is not the Department's burden to anticipate future discovery. With discovery of the investigative file, interrogatories and requests for production answered, the Department has no other information to provide. Of course, deposition may or may not be helpful, but that is not a basis to extend the time for answering the amended charges. Therefore, using discovery to justify delaying an answer is not contemplated by the statute.

Two Charges, Same Investigation

The information in both sets of charges is based on one investigation. No new information was gathered in order to expand the disciplinary charges against Dr. Ames. Simply put, the Department, in ongoing discussions with its legal team, determined that the same investigation supported other charges, so the charges were amended. Nothing improper or unethical was done with the amendment of charges. WAC 246-11-260. The Answer form to the charges provides four types of responses to give in reply to charges filed. Respondent can either "Admit," "Deny" or "Do Not Contest" the charges. The last option

provides an opportunity to add an additional statement with any information desired by the responding party. Dr. Ames can do either within the 20-day deadline. Only if he demonstrates hardship, can he delay that deadline. Dr. Ames' reason for delay does not fall within the statute's intent or purpose.

The Answer is not to prove your case with all of the information available in order to overwhelm the charges put forth. The Answer is only to provide a position with an opportunity for additional information. Dr. Ames already had an opportunity to provide any information he wanted when the Department sent him a notice that a complaint was filed. See Department's Notice of Investigation. Dr. Ames admits that the Amended Statement of Charges (second SOC) was similar to the complaint filed in the first Statement of Charges. If so, then Dr. Ames had the same motivation to gather information for the first SOC as the second SOC. The Department sent Dr. Ames notice of the complaint on September 28, 2001. Attachment 5. Since all charges spring from the same information sent to Dr. Ames since September 2001, how has he been prejudiced by answering within 20 days as required by the statute? WAC 246-11-270(1)(a)(i). He has not been prejudiced based on the information in his motions. Essentially, Dr. Ames has not provided reasonable grounds for delaying the answer to the second SOC. He should answer them now.

Deponent Available for Deposition

If Respondent wants to conduct discovery, the Department is not standing in his way. But discovery of relevant and proper subjects should only be permitted. Consultants to the Department, who will not testifying at hearing, are not proper subjects for his discovery. The information needed to answer the amended charges has been in Dr. Ames' possession since

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V. ORDER

Based upon the above, along with the files and records in this matter, the Presiding Officer hereby issues the following ORDERS:

5.1 The Department's Motion to Quash the depositions of James Rich, PA-C, and Randi Leggett, M.D., is GRANTED; accordingly, the Notice to take the depositions of James Rich, PA-C, and Randi Leggett, M.D., in this matter, are QUASHED.

5.2 Consistent with the above Conclusions of Law; the Respondent's request for remedial relief is DENIED in part and GRANTED in part; accordingly, the Respondent shall be permitted to depose the Complainant. The Department shall contact the Respondent to arrange for the Complainant to be deposed between April 1, 2003 and April 21, 2003. If such arrangements present an undue hardship or is burdensome, the Presiding Officer shall resolve the issue upon receipt of motion and response.

Dated this 25th day of March, 2003

/s/ *Arthur E. Debusschere*
ARTHUR E. DEBUSSCHERE,
Health Law Judge
Presiding Officer

DECLARATION OF SERVICE BY MAIL

I declare that today I served a copy of this document upon the following parties of record: ***WILLIAM BISHIN, ATTORNEY AT LAW AND KEITH ARMSTRONG, AAG*** by mailing a copy properly addressed with postage prepaid.

DATED AT OLYMPIA, WASHINGTON THIS 25 DAY OF MARCH, 2003.

/s/ [*Signature*]
Adjudicative Clerk Office cc: **LISA NOONAN**

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice As a Physician and Surgeon of GEOFFREY S. AMES, M.D. **License No. MDOOO26961** Respondent.	)	Docket No. 02-06-A-1012MD **MOTION TO DISMISS STATEMENT OF CHARGES** (Filed May 28, 2003)

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STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice As a Physician and Surgeon of GEOFFREY S. AMES, M.D. **License No. MD00026961**	Docket No. 02-06-A-1012MD **MOTION TO DISMISS STATEMENT OF CHARGES**

Respondent Geoffrey S. Ames, M.D. hereby moves for an order dismissing in its entirety the First Amended Statement of Charges on the ground, *inter alia*, that this proceeding conflicts with the Federal Food Drug and Cosmetics Act ("FDCA"), as amended by the Medical Devices Amendments of 1976 ("MDA") (sometimes collectively referred to as "FDCA") and regulations of the Food and Drug Administration ("FDA"), that the Commission is therefore without authority and lacks subject matter jurisdiction to initiate or entertain such a proceeding and that continuing prosecution before an incompetent tribunal is a continuing deprivation of Respondent's liberty and property without due process of law. In the

alternative, Respondent moves for an order disposing of each charge that admits to being, or is necessarily, a charge based on a violation of the FDCA, the MDA and FDA regulations and disposing of such other claims as the Presiding Officer or the Commission finds as a matter of law to be unsupported by evidence that a fair minded, rational person could reasonably conclude was clear and convincing evidence of the validity of such a claim.

FACTS

The Department filed a Statement of Charges ("Statement") alleging that Respondent had tested a patient ("P1") for allergies using a device called the LISTEN. The Statement alleged that Respondent's acquisition of the LISTEN violated the Federal Food, Drug and Cosmetic Law ("FDCA") because, it alleged, the LISTEN had not been approved or otherwise cleared for marketing by the Food and Drug Administration ("FDA"). Because of the alleged absence of an FDA clearance, the Statement alleged, Respondent had violated 21 U.S.C. §331(c) of the FDCA, because, it alleged, Respondent had received the device in interstate commerce. The failure to obtain such an FDA clearance, the statement further charged constituted a violation of 69.04 RCW, the state food and drug law. The Statement of Charges pleaded in the alternative that if the LISTEN did have a clearance from the FDA, Respondent did not use it for the purpose that the FDA had cleared for marketing. The Statement was silent as to what

section of either the federal or state statutes Respondent would have violated if he had used it for a purpose that had not been approved by the FDA.

By allegedly violating the food and drug laws cited, the Statement charged, Respondent had violated RCW 18.130.180(7), because the food and drug laws were, it claimed, laws "regulating the profession in question." No other violation of the Uniform Disciplinary Act was charged.

The Statement acknowledged that the manufacturer of the LISTEN had received a pre-market clearance for a device it called a Digital Conductance Meter ("DCM") and that a component of the LISTEN was a DCM. But, it alleged, the LISTEN had more features than the DCM that was cleared by the FDA, particularly more software, and was therefore a "new" device requiring its own clearance.

The Statement did not allege – and it has not been claimed at any time in this proceeding – that the FDA has ever proceeded against the manufacturer for failing to

* * * *

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: GEOFFREY S. AMES, M.D., License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD PREHEARING ORDER NO. 6: ORDER DENYING MOTION TO DISMISS

APPEARANCES:

Respondent, Geoffrey S. Ames, M.D., by
Law Offices of William R. Bishin, P.S., per
William Bishin, Attorney at Law

Department of Health, by
The Office of Attorney General, per
Keith D. Armstrong, Assistant Attorney General

PRESIDING OFFICER: Arthur E. DeBusschere,
Health Law Judge

The Respondent filed a Motion to Dismiss on May 28, 2003. Motion Denied.

ISSUES

Is this disciplinary proceeding, or any part of it, pre-empted by the Federal Food Drug and Cosmetics Act (FDCA), under the rationale of *Buckman Co. v. Plaintiff's Legal Committee,* 531 U.S. 341, 121 S.Ct. 1012 (2001)?

Are the allegations of the Statement of Charges or the evidence on which it is based sufficient to establish any violation under RCW 18.130.180(7), specifically RCW 69.04.040(1) & (3)?

Are the allegations of the Statement of Charges or the evidence on which it is based sufficient to establish any violation under RCW 18.130.180(1), (4) and (16)?

SUMMARY OF DECISION

The holding in *Buckman* does not apply to this disciplinary proceeding. There are genuine issues of material fact whether the Respondent's conduct under

* * * *

[The Remaining 11 Pages Of The Order Have Been Omitted]

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL CARE QUALITY
ASSURANCE COMMISSION

In the Matter of the License to Practice Medical License of: GEOFFREY S. AMES, M.D., License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD DEPARTMENT'S *AMENDED* PREHEARING STATEMENT (Filed Jul. 10, 2003)

COMES NOW the State of Washington, Department of Health, Dental Quality Assurance Commission (Department), by and through its attorneys, CHRISTINE O. GREGOIRE, Attorney General, and KEITH D. ARMSTRONG, Assistant Attorney General, and provides the following Amended Prehearing Conference Statement.

I. AMENDMENTS TO PLEADINGS

The Department does not anticipate any amendments to the pleadings at this time.

II. UNRESOLVED DISCOVERY

The Department has no unresolved discovery.

III. STATEMENT OF FACTS

The Department incorporates by reference the factual allegations set forth in the Statement of Charges Section 1.

IV. STATEMENT OF ISSUES

The following ultimate issues are to be decided at hearing:

1. Did the Respondent engage in unprofessional conduct as alleged under RCW 18.130.180(1), (4), (7), (16); RCW 69.04.040(1) and (3); 21 U.S.C. § 331(c)?

2. If unprofessional conduct is proven by the Department, what is the appropriate sanction under RCW 18.130.160?

V. WITNESSES

The Department intends to call Respondent as an adverse witness.

The Department may also call all or some of the following witnesses, in any order, in person or by telephone:

1. Patient One, Complainant.
2. Neil Ogden, Director, Center for Devices and Radiologic Health and General Surgery, Federal Drug Administration (301) 594-1307.

3. Rich Sherman, PhD., Research Physiologist, Chief Consultant for Research, Orthopedic Surgery, Madigan Army Medical Center, Tacoma.

4. Department of Health Investigator, Joseph Grangnelli, BSN, RN. Investigation/Legal Unit.

The Department reserves the right to call in its case in chief any witness identified by Respondent. The Department reserves the right to call rebuttal witnesses who may or may not be identified in its witness list. The Department further reserves the right to amend its witness list for good cause shown.

VI. RELIEF REQUESTED

The Department requests affirmance of the violations alleged in the Statement of Charges and the imposition of appropriate sanctions.

VII. EXHIBITS

The Department may submit all or some of the following exhibits:

1. Documents provided by Patient One:

   a. July 31, 2001 memo from Patient One to MQAC recounting his experience with Respondent, INV.00246-47.

   b. July 12 & 16, 2001 email correspondence between Patient One and Sharon Seidel, DHS-EHIB, regarding

Seidel's JAMA article on hair analysis for lead, minerals, INV.00258-59.

2. Patient One's Medical Records, INV.00299-348.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY
ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: GEOFFREY S. AMES, M.D., License No. MD00026961 Respondent.	Docket No. 02-06-A-1012MD PREHEARING ORDER NO. 8: ORDER ON OBJECTIONS TO EXHIBITS

APPEARANCES: Respondent Geoffrey S. Ames, M.D., by Law Offices of William R. Bishin, P.S., per William Bishin, Attorney at Law

PRESIDING OFFICER: Arthur E. Debusschere, Health Law Judge

The Presiding Officer considered exhibits offered for admission and the objections submitted.

I. PROCEDURAL HISTORY

The hearing in this case was scheduled for July 25-26, 2003. The Presiding Officer conducted pre-hearing conferences on July 11, 2003 and July 17, 2003. The Department filed a Prehearing Statement and the Respondent filed a Prehearing Memorandum, in which the parties identified their witnesses and exhibits. The parties also filed motions in limine,

which included objections to exhibits and witnesses. The deposition of a Department's witness was also being scheduled, but delayed, due to scheduling with a federal FDA (Food and Drug Administration) employee. The Presiding Officer granted the Department's motion to continue the hearing. The Presiding Officer set briefing schedules for responses and replies to objections.

Based upon the filings and argument of counsel, the Presiding Officer hereby issues the following:

II. ISSUES AND SUMMARY OF ARGUMENTS ON THE ISSUES

Issue A and Issue B are the two primary issues for the hearing:

Issue A Did the Respondent engage the unprofessional conduct in violation of RCW 18.130.180(1), (4), (7) and/or (16)? Under RCW 18.130.180(7), did the Respondent violate a state statute, specifically RCW 69.04.040(1) and (3), and/or violate a federal statute, specifically 21 U.S.C. § Section 331(c)?

Issue B If the Respondent engaged in unprofessional conduct, then what sanction(s) as authorized by RCW 18.130.160 should be imposed?

The issues arose from Respondent's treatment of Patient One on July 10, 2001. The charges alleged that by using a LISTEN device on Patient One to diagnose food allergies, the Respondent violated the Uniform Disciplinary Act (the UDA), chapter 18.130,

RCW, specifically RCW 18.130.180(1), (4) and (16). The Statement of Charges alleged that the Respondent's medical device was called the Life Information System Ten device (the LISTEN device). The Statement of Charges also alleged that the Respondent violated RCW 18.130.180(7), because he used an adulterated or misbranded medical device in violation of 21 U.S.C. § 331(c) and of RCW 69.04.040(1) and (3).

Summary of Department's Argument on the Issues.

The Department maintained that when the Respondent treated Patient One, he used the LISTEN devise to diagnose food allergies. The Department argued that the LISTEN device was similar to other EDS (electro dermal screening) devices, which have not been approved by the FDA to be marketed or used in the practice of medicine. The Department argued that by using the LISTEN device in this manner, the Respondent violated RCW 18.130.180(1), (4), (7) and (16).

The Department also maintained that the Respondent recommended chelation therapy as a result of a hair analysis of a single strand of hair. The Department argued that by ordering this hair analysis, the Respondent violated RCW 18.130.180(1), (4) and (16).

In response to the Respondent's contentions, the Department argued that the LISTEN device was not a DCM (digital conductance meter). The Department

refuted the Respondent's claims that he treated Patient One with biofeedback or with any Chinese treatment such as acupuncture or acupressure.

Summary of Respondent's Argument on the Issues.

The Respondent argued that Patient One's testimony would not support the Department's claims. The Respondent maintained that he did not use the LISTEN device as the Statement of Charges alleged and as argued by Department's counsel. The Respondent argued that he treated Patient One with acupressure, not by the LISTEN device. Further, the Respondent would also testify that the Listen device was not used for EDS screening or to treat patients.

* * * *

OPENING STATEMENT BY MR. ARMSTRONG

[2052] JUDGE DeBUSSCHERE: That was the first exhibit. I imagine it's –

MS. PAXTON: The letter to the FDA?

JUDGE DeBUSSCHERE: No, it's a letter that I removed, so the first exhibit of the Respondent's packet, yes, a letter to FDA dated 8/18/92, that was removed and will be provided, provided that the proper foundation is made.

The parties will be referring to their exhibits during the hearing, so the commission members have that copy so that they can refer to those exhibits during testimony. Also each Panel members has a copy of the Respondent's hearing brief. With that it's now an opportunity for opening statement. Go ahead, Mr. Armstrong, you're first.

* * * *

OPENING STATEMENT

BY MR. ARMSTRONG:

Thank you. Good morning Panel and Judge DeBusschere. I'm going to start my opening statement talking about doctors, since that's the subject of our disciplinary hearing.

Doctors are a lifeline to everybody in this room, and they're respected, with high character, and moral standards. Because of that we believe what [2053] they say. We listen to them. We rely on their

judgment and their expertise, and why not, their lives are on our hands.

My name is Keith Armstrong. I'm an assistant attorney general representing the Department in this case. I'm going to be presenting the case, and Respondent here is Doctor Geoffrey Ames, about his professional practice as a doctor east of the mountains.

Today's evidence is going to focus on a practice that's below the standard of care for Washington. It's a practice that the Department received a complaint, investigated and determined that it was unprofessional conduct, and we're bringing the evidence to you to determine if that is truly the case.

We have a Statement of Charges that has details about one patient and a device. That device stands right there to my left and to your right. That is the LISTEN device, and I'll talk more about that later. The evidence that we intend to show for these few days is that Doctor Ames abused his position as a physician. We're going to show evidence that he performed techniques and used that electronic device to practice medicine. The [2054] Department is alleging, there are charges that this device is not a proper use of his medical expertise, is not a proper device to be used in medical practice. We're going to present four witnesses to prove our case. The first I'm going to have Doctor Ames himself come and talk about his care with Patient 1 and his practice. Next I will have, who's in route now from Pasco, is Patient 1.

He should be here at any time now. He is a certified industrial hygienist who works for the federal government over in the Hanford area. He will be talking about his care provided by Doctor Ames.

Next we're going to have, in this order we're going to have Doctor Richard Sherman. He's a research physiologist. He is the chief consultant for research for orthopedic surgery at Madigan Army Medical Center.

Last we're going to have Neil Ogden. He's the branch chief of the general surgery devices branch and radiological general surgery at the Food and Drug Administration. He is the branch chief of that. His division evaluates this type of machine to determine if it's a proper machine to be marketed, cleared for whatever purposes, so we're going to have his testimony by phone. The rest of them will be [2055] here in person.

Those four individuals, counting the Respondent, will be the total of the Department's case. The evidence that we have in document form, we have Doctor Ames' statement as a response to the investigation, and we have the patient's records, so we have his medical records here for you all to review, and I'll be making some reference to that.

Other than that, that will be the total sum that you will see from the Department as far as Doctor Ames' practice with Patient 1, but also we'll be talking in general about his practice of medicine. That will be the subject.

This case is going to talk about his practice with this machine, principally. That's what it's going to deal with.

My opposition is attorney Mr. Bishin. They're going to present testimony to rebut our case, that using this machine in the practice of medicine is below the standard of care, and you're going to have topics and evidence from all kinds of experts on all types of topics, none dealing with allergy treatment.

MR. BISHIN: With what?

MR. ARMSTRONG: Allergy treatment. [2056] This case is going to be principally, one principal issue is whether Doctor Ames' treatment of allergy with Patient 1 was legitimate, efficacious or inefficacious, or whether it was below the standard of care or at the standard of care.

The defense is going to rebut the Department's case by claiming that the machine is registered by the FDA and all they're doing is off-label use. The Department's witnesses will debunk that idea, that the device is not registered by the FDA. The Department's evidence is going to show it is not approved by the FDA and it's not cleared by the FDA, not only to not treat allergies, but the evidence is going to show it is not cleared to treat anything.

My opposition's rebuttal is going to try to talk about a lot of other subjects other than allergy treatment by a physician. I ask you not to listen to that evidence. Once you hear from –

MR. BISHIN: I object to that, Your Honor.

JUDGE DeBUSSCHERE: I'll sustain the objection. It is argumentative.

MR. ARMSTRONG: Let me say it this way: None of the evidence that my opposition will bring [2057] will overcome what the FDA has to say, and that's the only person who can make the determination whether this machine is authorized or not. They may try to divert your attention with other type of methodologies of treatment. I ask you to focus on the issue of treatment of allergies for Patient 1. The Department is going to show evidence that Doctor Ames used his medical license to entice patients into unorthodox, unproven, unauthorized and inefficacious treatments without the informed consent or knowledge of the risk of these treatments.

The Department is going to show evidence that his care for these patients was not at the standard of care for professional doctors, but below that.

The credibility of the witnesses is going to be very critical. Patient 1's credibility is going to be very critical in this case. Doctor Ames' credibility is going to be very critical, but what I want you to focus on is after you have heard those two individuals, I would like you to focus on what the FDA has to say, because they're going to have the ultimate conclusion on what the device can do and what it cannot do. So if it doesn't come from the FDA, I don't think they will have anything to [2058] say, once this case is over. That's the story of this case, Doctor Ames treating

Patient 1 for allergies, whether that was appropriate or not, and his types of treatment.

I ask the Commission to listen to their evidence and listen to our evidence, and at the end of the day their evidence is not going to hold water to what Patient 1 and the FDA has to say. Thank you for your attention this morning.

JUDGE DeBUSSCHERE: Mr. Bishin, your opening statement?

MR. BISHIN: Yes, Your Honor. Thank you.

* * * *

OPENING STATEMENT

BY MR. BISHIN:

My name is William Bishin. I represent Doctor Geoffrey Ames in connection with this matter that you're going to be hearing and deciding. This case is, in an important sense, a case about Doctor Ames' use of this particular device. In fact it certainly is the way the Statement of Charges reads. You'll see that almost all of it is about this particular device, and a large part of the statement of Charges refers to and tries to paraphrase portions [2059] of the Food, Drug and Cosmetic Act. There are a number of things that arise in this case that are extremely misleading, and we're going to try to alert you to that.

You have just heard the Department say that what the case is about is a physician who was practicing below the standard of care for treating

allergies, and you have also heard him say that what the case is about that the FDA witness they're going to have testify has the final say on that, that this individual is the expert on this issue.

Now on the face of that it seems to me you should be able to see, even from the statement, but certainly from the evidence that will be presented that that is not true and could not be true.

The individual who is going to testify for the FDA is a midlevel official who calls himself the lowest level of management in a particular part of the Food and Drug Administration. He is not a physician. He does not have a medical degree. He has never practiced medicine. He has never treated allergies. He is a biomedical engineer. That's what his degree is in, and his job has been to review devices that come to the FDA and make certain

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[1985] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD DAY 1 ORIGINAL

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

HEALTH LAW JUDGE:
ARTHUR E. DeBUSSCHERE

FOR THE RESPONDENT:
WILLIAM R. BISHIN
Attorney at Law
701 Fifth Avenue, Ste. 4040
Seattle, Washington 98104

FOR THE DEPARTMENT OF HEALTH:
KEITH D. ARMSTRONG
Assistant Attorney General
1125 Washington St. S.E.
Olympia, Washington 98504

COMMISSION MEMBERS PRESENT

SUNANDA UBEROI, M.D. JANICE PAXTON, PA-C

CABELL TENNIS, J.D.
Public Member

Renton, Washington
January 13, 2004

REPORTED BY JEAN ERICKSEN, CCR

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* * * *

DIRECT EXAMINATION OF DR. AMES

[2084] A. I never used the device with Patient 1. I did tell Patient 1 I do have a device.

Q. Were those your exact words?

A. No. Those aren't my exact words.

Q. Do you remember what your exact words were?

A. My exact words are that I own a LISTEN machine which is a galvanic skin response machine that oftentimes I use to assess imbalances in acupuncture meridians.

Q. So you told the patient this?

A. Yes, I told the patient this.

Q. What was the reason for telling the patient about this machine if you weren't going to use it?

A. I told the patient about this on July 10th, '01, and I told him that I do a therapy called NAET, and I oftentimes use this machine to assess imbalances in acupuncture meridians.

My primarily assessments for allergies would be to take a detailed history. Usually patients tell me what allergy they have, or they can adduce or almost adduce from a detailed history of what allergy they have.

I also do extensive allergy blood testing. The machine plays a minor role in allergy assessment. I do not diagnose allergies with this machine.

* * * *

[2098] of five ohms, but I'm not the inventor of the machine, so I can't really give you a reliable answer on that.

Q. What's your understanding of it?

A. My understanding is that it is mainly used as a galvanic skin response machine to measure differences in acupuncture point resistance.

Q. You were going to have, as part of your defense you're going to have two patients come in to testify on your behalf. Are these patients that you have used, you have treated for allergies?

A. Yes.

Q. Did you use the LISTEN device in your assessment of their allergies?

A. As part of my assessment of allergies I have used it sometimes on these patients.

Q. Okay. How did you use it with these patients?

A. I do a kinesiology technique. The patient holds this in their right arm and I test their left deltoid muscle strength.

Q. How do you test their strength?

A. The patient will hold their thumb towards their left big toe, and I'll gently pull down on their arm.

[2099] Q. Let me slow you down, Doctor, because I understand exactly what you're saying, but I want to make sure the record is clear. You're saying in the right hand you're holding the metal probe?

A. Correct.

Q. And you're raising your left hand?

A. The patient is.

Q. The patient is raising their left hand. What you do is you pull down on raised left hand to see what?

A. To see if there is a weakness in the deltoid muscle.

Q. And if there is a weakness, what does that mean?

A. It may mean that the patient naturally has a weak deltoid muscle, and that would not be a good indicator muscle to use, or it may mean that there is imbalance in the acupuncture meridian making that muscle weak.

Q. What would cause an imbalance?

A. An allergy could cause an imbalance or an illness, or arthritis in the joint of that muscle, or muscle disease or muscle injury.

Q. Can the LISTEN device determine what -is an allergy imbalance versus another imbalance?

[2100] A. No, the LISTEN device cannot do that.

Q. These patients who are coming to testify on your behalf, they're going to be talking about your medical treatment that you provided, correct?

A. Yes.

Q. This would be medical treatment in the very recent past, or far, before you had the LISTEN device?

A. Since I have had a LISTEN device, I have treated these patients, but I don't usually use a LISTEN device on most of the allergies, because these patients will bring in their own allergies from their own yards or from the neighborhood, and then I use those to do the acupressure treatment on these patients.

I mainly do not use the device on these patient, but I have used the device in the past on these patients.

Q. What percentage of patients, if you can just give me a round number, that you use the LISTEN device to help assess allergies?

A. What percentage of allergy patients that I see?

Q. Yes.

A. It might be around 50 percent.

* * * *

[2103] Q. But they have been misplaced, or what happened to them?

A. I can't find the manuals any more. They have been misplaced.

Q. But you received training from an individual, you just didn't take the manuals and learn on your own, you got your training from someone else?

A. I got my training from my nurse who I sent to take the course.

Q. I'm going to approach the device. Doctor Ames, I'm looking closely at this device. I'm looking at the tower, and I can't see on the back of it. Does this machine have any specific warning labels or anything on it, that tells you don't do this or don't do that with the machine?

A. I do not know.

Q. I didn't see any. I was wondering if you knew of –

A. I haven't seen any warning labels, but I haven't really looked for warning labels. I haven't looked in close detail.

Q. When you bought this machine in 1997, did it come with any labeling to show you what it does, or indicate to you what it does?

* * * *

[2112] A. Oh, imbalance, yes.

Q. Okay. How do you re-balance that?

A. With a lie detector machine?

Q. No, with a galvanic skin device. How would a galvanic skin device, it can detect the imbalance, can it re-balance?

A. I don't know.

Q. Okay, to the best of your understanding, it cannot?

A. I just don't know. I don't have an understanding.

Q. Okay. The LISTEN device that you use, do you use it to read imbalances in the skin of patients?

A. I use the device with kinesiology to measure weaknesses in the muscles.

Q. Is that different from reading imbalances in energy levels in the skin?

A. Yes.

Q. What is the difference between what you said, kinesiology, versus reading imbalances in their skin?

A. Some practitioners will use a machine as an Electrodermal screen instrument. I do not use the machine that way. I use the machine in combination [2113] with kinesiology.

Q. Electrodermal screening?

A. Some practitioners will use it that way.

Q. Do you have an understanding of what that is?

A. Yes.

Q. What is that?

A. Electrodermal screening technique is where a practitioner probes different acupuncture points and gets readings.

Q. Isn't that similar to what you described the LISTEN device does?

A. That is one use of the LISTEN device.

Q. But you don't use it that way?

A. No, I don't use it that way.

Q. You didn't use it that way with Patient 1?

A. I never treated Patient 1.

Q. And you didn't use that with the two patients who are coming in to testify at this hearing?

A. Correct.

Q. So no EDS on any of the patients, Patient 1, or the other two patients?

A. I have never used EDS in my practice on any patient.

* * * *

[2141] Q. What do you do use it for?

MR. BISHIN: Objection. Asked and answered. I'll withdraw that. There has been a lot of confusion. I'll let him ask the question.

JUDGE DeBUSSCHERE: Go ahead, Mr. Armstrong. You asked Doctor Ames what does he use the LISTEN device for.

A. I use the LISTEN device to detect weaknesses in people's muscles, specifically their deltoid muscle.

Q. Is that it, is that the only use you use the LISTEN device for, to detect weakness in muscles, you don't use it for anything else?

A. No, I just use the LISTEN device to detect weaknesses in muscles.

Q. In detecting that weakness are you making it similar to finding an imbalance in that muscle; is that the same, are you making those similar or equivalent terms?

A. I don't know what you mean by balance.

Q. Imbalance.

A. Please repeat the question.

Q. When you use the term detect weaknesses in the muscles, I'm asking is that equivalent to finding an imbalance in energy flow in that muscle?

[2142] A. That is equivalent to finding an imbalance in their acupuncture meridians.

Q. Do you use the LISTEN device to restore this balance in the acupuncture meridians?

A. No, of course not.

Q. Let me ask you, Doctor, if you misdiagnosis a patient in treating them for allergy, could that patient be harmed?

MR. BISHIN: Do you mean him, or anybody?

MR. ARMSTRONG: I said him.

A. Repeat the question.

Q. If you, as a medical practitioner, diagnosed the patient, say Patient A, you diagnosed him for egg allergies, and you, in your assessment, determined he doesn't have egg allergies, and he goes –

A. You just said, you conflict yourself. You said I diagnose the patient with egg allergies, and you just said, I haven't diagnosed egg allergies. I don't know what your question is.

Q. Let me repeat it. If you, as a medical practitioner, diagnosed a patient, say Patient 1, for

egg allergies, all of your testing and information, you have diagnosed egg allergy is present in this person.

[2143] A. Yes.

Q. But you have mis-diagnosed it. If that patient goes off and encounters eggs, could he be harmed by that mis-diagnosis?

A. First of all there are two type of main allergy testing. There are IgE antibody testing and IgG. IgG tests for delayed allergies which could happen minutes or a day later.

IgE testing tests for meat allergies which can cause anaphylaxis and death. I never tell somebody that they have an allergy. I tell them I suspect that you have allergy, and the patient isn't going to come in and tell me they have a life-threatening allergy. They'll say I'm allergic to peanuts, I ate a peanut and I almost died, or I got stung by a bee and I almost died or I could die, they'll tell me that.

So a delayed allergy will not cause a life-threatening condition, it's just an immediate allergy, and IgE allergy that may cause a life-threatening condition.

Q. Okay. my question was can a patient be harmed if you mis-diagnose whichever allergy testing you use?

A. No, they cannot be harmed, because the [2144] patient is already eating that food in the first place. They're already exposed to allergy.

Q. Did you tell Patient A that he was allergic to eggs?

A. I told Patient A – Patient 1, you mean?

Q. Patient 1, sorry.

A. I told Patient 1 that the blood test shows egg allergy. Let me look at my blood test results here. That would be the Interpath Laboratory page where egg yoke is at the very top.

JUDGE DeBUSSCHERE: Can you show that lab report again.

THE WITNESS: Here, this is it. It has egg up at the top.

Q. That would be Exhibit 2, page 12.

A. The prior page of my notes has egg white on a separate page.

Q. That would be page two, Exhibit 2, page 12. I don't have the number.

JUDGE DeBUSSCHERE: The page before is Exhibit 2, page 11.

THE WITNESS: Correct.

JUDGE DeBUSSCHERE: What was your question, Mr. Armstrong?

Q. Did you tell Patient A that he was allergic

* * * *

[2154] don't have an allergy, because there is no test that is a hundred percent sensitive or specific to detect allergies, so I don't know.

Q. That's all I have now. Thank you.

JUDGE DeBUSSCHERE: Any redirect on the questions asked, Mr. Armstrong?

MR. ARMSTRONG: Yes, I have just one or two.

* * * *

REDIRECT EXAMINATION

BY MR. ARMSTRONG:

Q. You mentioned, Doctor Ames, that you used the LISTEN to detect, as an assessment. You mentioned that you used the LISTEN to create an imbalance in the muscle. Could you elaborate on that?

A. Yes. when a patient has an imbalance in an acupuncture meridian, the muscle usually weakens. Therefore when I do muscle testing, the arm will go down when I pull down on the arm.

Q. You use the LISTEN machine to make that muscle weak?

A. I also use other ways to make that muscle weak. Patients can bring in allergy samples, but I do use the machine for that purpose.

[2155] Q. How does the machine make the muscle weak?

A. Theory is – this is only a theory – imbalance in acupuncture meridians will make muscles weak.

This was discovered by Doctor Goodheart, a chiropractor, in 1971. Acupuncture has been around for a thousand years. The Chinese never knew that an imbalanced meridian can make the muscles weak, they never discovered kinesiology. It was discovered in 1971 by Doctor Goodheart, and a whole field of kinesiology has developed from this.

Q. Let's see if I understand this correctly, if you know how this works. If the machine makes the muscle weak, would you agree with this statement that the LISTEN machine takes the electrical energy and it flows it to the muscle, would that be correct, in order to balance that meridian?

A. The LISTEN machine is sending a signal, and the signal is a digital signal that affects the acupuncture meridians. when the meridians are out of balance, muscles usually become weakened.

Q. Now, when you say send a signal, would that be equivalent to electrical energy, would you say it sends a signal to the muscle, is that equivalent to electrical energy going to that muscle?

* * * *

[2158] **EXAMINATION**

BY MR. TENNIS:

Q. You mentioned NAET testing. I'm a public member. Tell me what that is.

A. NAET testing stands for Nambudripad Allergy Elimination Technique. Dr. Nambudripad is a registered nurse, an acupuncturist and a chiropractor, and she developed NAET. It is a technique that is very successful at eliminating allergies using acupressure.

JUDGE DeBUSSCHERE: Could you state that again?

THE WITNESS: The NAET technique is a very successful technique in eliminating allergies using acupressure.

Q. Acupressure is a form of –

A. Acupuncture, that's correct.

Q. Uses the same points?

A. Same points, that's correct.

Q. And that machine, as you showed us earlier, is part of what you use for that?

A. This device right here?

Q. Yes.

A. Right.

Q. You mentioned in talking about how you [2159] detect the weakness in the muscle through the use of a LISTEN device, you mentioned that you typed in something. I assume you mean the keyboard. Would you say a little more about that?

A. Sure. I'll type in different suspected allergies. Very common food allergies would be eggs, dairy, wheat, soy, corn and sugar, so I'll type in different foods, and then I'll see if I get a weak response in the muscles.

Q. Okay, so you type it into the computer?

A. Correct.

Q. And the computer in turn sends an impulse of some kind to the –

A. Hand.

Q. You're not using another sensor, so it's not connecting a loop, a circuit?

A. No, it is not.

Q. Earlier on you mentioned that impedance resistance is in a circuit. That's good electrical high school physics.

A. Right.

Q. I don't see the circuit. How does it measure resistance when you, don't have a circuit?

A. Because the signal is actually –

MR. BISHIN: I want to object to the [2160] question. Forgive me. He didn't say that it measured resistance. He said that it weakened the muscle.

MR. TENNIS: Earlier on I believe he –

MR. BISHIN: The question just now – yes, he did testify to that. That's a different thing. What I'm saying is that your question now just assumes that he's measuring resistance when he does this, and I'm just objecting to that, because that was not his testimony.

MR. TENNIS: All right.

JUDGE DeBUSSCHERE: I'm not overruling his objection. You may want to restate your question.

MR. TENNIS: Sure.

I'm just trying to find out your understanding of what happens when you type in egg, eggs. What's your understanding of what happens in this machine?

A. My understanding of what happens is that if the person is actually allergic to egg, there will be an imbalance in their acupuncture meridian, and that imbalance will cause a weakening in different muscles.

Q. How do you determine weakness in the muscle?

[2161] A. I usually just test one indicator muscle and that would be the deltoid, so I have the patient lift up their arm, and I gently pull down on their arm.

Q. You previously established the strength of that muscle?

A. Right, as a control.

Q. Is it your experience when you type in different possible allergens, you get a different response?

A. Yes.

Q. That's all for me now.

JUDGE DeBUSSCHERE: Doctor Uberoi?

DOCTOR UBEROI: Yes, I have a few questions.

* * * *

EXAMINATION

BY DOCTOR UBEROI:

Q. How did you hear about this device, where were you?

A. At my conferences that I go to, other colleagues used devices like this, or the same device, and I heard about it from colleagues.

There's also vendors who sell these devices at these conferences, so I would go around and talk to vendors.

[2162] Q. Was this an acupuncture conference or naturopathic or allergy?

A. The American Academy of Environmental medicine.

Q. I don't know if I can ask this. There must be a cost for this equipment, a thousand dollars or whatever, x number of dollars?

A. Yes.

Q. Can you charge for the use of this equipment?

A. I have never charged for the use of this equipment, ever.

Q. So you just hope that it will help you with your diagnosis, whether you recoup the money that you have spent on it or not?

A. It helps me with my assessment, and it helps me with my assessment. I don't expect to recoup the money.

Q. It would help you with a more accurate assessment or speedier assessment?

A. It actually helps speed my assessment. would you repeat your question, again?

Q. Does it help you with a more accurate assessment or speedier assessment; I mean do you save time or do you make a better or more efficient [2163] diagnosis?

A. I can make a more efficient diagnosis, because, like I explained before, I do extensive history-taking, I do blood work and I do NAET testing, so I put the whole picture together, so it's part of the whole picture. It also saves me time.

Q. Where is the device made, is it made in the U.S., or is it corning from China?

A. It's made in Utah.

Q. Do you tell the patients that you're going to do this as part of your assessment, before you use it?

A. Before I use this machine I explain to my patients a general theory on how the LISTEN machine works. Also I explain to my patients NAET, I demonstrate it on every patient before I do NAET.

Q. NAET is also treatment, so you use the same machine for treatment, also?

A. No, this machine doesn't treat. Acupressure treats. This is the instrument that I use to treat patients. I don't use this machine to treat any patients.

Q. That's part of the NAET?

A. You can use a chiropractor activator machine or you can use an electronic one. After using a

[2164] manual chiropractic activator machine I was getting repetitive injury on my arm, so I decided to go with the electronic version.

Q. Would you consider this as evidence-based medicine for the ER branch of medicine? I'm not a naturopath or I'm not a kinesiologist. Is there enough support like in the regular medicine we have, evidence-based medicine?

A. Okay. There are hundreds and hundreds of NAET practitioners getting successful results with NAET, so a true scientist has an open mind and they're willing to look at any objective evidence, if it's there, and then they can make up their own mind.

So my colleagues get very good results with NAET, Doctor Nambudripad, who invented it, gets very good results, and I get very good results, so it works, and my patients tell me it works.

Q. You took the acupuncture course at UCLA at San Francisco?

A. Yes.

Q. This is not part of the Helmes course?

A. Correct. Helmes teaches the use of other acupuncture devices.

Q. This is not part of that, this is an off-shoot from kinesiology?

* * * *

[2173] convenient.

Q. What other muscles might –

A. I could use leg muscles, for instance, or I could use hand muscles, finger muscles, break apart the finger, but the deltoid muscle gives us reliable testing.

Q. And how do you know that?

A. Because my colleagues and Doctor Nambudripad have tested thousands of allergens, and we find that the muscle testing, the kinesiology correlates very well with blood testing.

Q. If you didn't know kinesiology, would the LISTEN device by itself be used?

A. I would not be using it.

Q. If it exists to indicate there is some disruption in the meridian, or imbalance I guess is the word I should use, by itself, without the use of kinesiology, would it tell somebody that?

A. I don't understand your question.

Q. Okay. You're using it in conjunction with kinesiology. If it's simply this unit exists to indicate an imbalance in meridians in order to then go on for treatment, why would somebody use this machine?

A. I still don't understand your question, I'm [2174] sorry.

Q. Let me try again. Does the machine by itself when you type in, we'll use eggs, since that's been the generic today, and the person hangs on to this and there is no testing of muscle strength, what does it tell you by just holding onto that probe and you have typed in eggs?

A. It doesn't tell me anything.

Q. That's what I wanted to know, okay.

When you first got into your alternative medicine profession, were you using the LISTEN device from the very beginning?

A. No, I was not.

Q, Why did you begin using it?

A. When one takes Doctor Nambudripad's course one can purchase homeopathic vials from her. My patients are so chemically sensitive or allergic that I didn't have enough vials to treat my patients or to test my patients, I mean test my patients in the use in the testing, so I decided to buy the LISTEN machine so I would have greater access to potential allergies.

Q. When you type in different allergens, the generic that we all kind of know that people could be allergic to, dairy, chocolate, strawberries, all that [2175] kind of stuff, eggs.

A. Common allergens.

Q. And you start with one, let's say you start with eggs and you move on and you test dairy, and then move on and test strawberries, is there, to your knowledge, residual problems in continuing to test the deltoid and weakening it so that you actually get a skewed response?

A. Yes, that could be the case, so we oftentimes change our muscles, and I only use two or three fingers in testing the deltoid, not really pressing really hard on the arm, but I always ask the patients are your arms weak, we can always try another arm.

(Interruption in proceedings.)

Q. How do you know by using the LISTEN device in concert with kinesiology and you find that there is a weakening in the deltoid muscle, that that is an allergy?

A. I don't know that. That's why I do other testing, blood testing and history testing. NAET treatment may be used to test, because if I suspect an allergy and I treat the patient with acupressure and the patient gets better, then I can suspect that that person had an allergy.

[2176] It's just like when somebody comes to a dermatologist and they have a rash, and you're not really sure if the rash is eczema or a fungal infection, so you give a steroid cream and the rash goes away, – and that helps to diagnose because you know that rash was caused by eczema, and not a fungus.

Q. That's a good analogy. You used a term that I just need clarification on. Homeopathic signal, can you describe what that is?

A. All of us give off energy, and that's been proven. All cells radiate energy. Homeopathic radiate energy too. They're diluted samples. Typical allergy shots are almost like homeopathics. They're real small dilutions, but they're still effective.

They still give off an electromagnet signal, so it's actually an electromagnetic signal that is given off by a homeopathic.

Q. In the use of the LISTEN device there's a certain amount of energy that has to come from that in order to weaken the muscle, I presume?

A. Yes.

Q. Okay. Would you consider that a voltage, or is –

[2177] A. Well, it depends on how allergic a patient is. As you know some people have mild food allergies, some people have severe food allergies, so a person with severe food allergies might generate a weaker muscle easier than somebody with just a mild allergy.

Q. I guess to understand my question, is there something coming from the LISTEN machine through the probe to the patient, in terms of any kind of voltage or electrical current?

A. There is a digital signal of whatever is typed in coming into the patient.

Q. Okay, and it's my understanding that according to your testimony, that there was never any information about whether that digital signal could be harmful to the patient, in the information you got when you got this machine?

A. Correct. Digital signals cannot harm any patient.

Q. And you know that because why?

A. Because they are homeopathic frequencies, and homeopathic frequencies cannot harm people.

Q. And you know it's a homeopathic frequency because?

A. The person who made the machine programmed [2178] homeopathic frequencies in a binary code into the computer.

Q. Now I guess what I'm trying to figure out is where does it say in the information you got that that's what's going on here?

MR. BISHIN: You're assuming it says that in the information you got. Are you talking about some kind of document?

MS. PAXTON: Yes, because, let me correct myself, if I haven't heard this right.

All the manual said was how to make the machine work, not what homeopathic information or signal or digital signal is coming from the machine?

MR. BISHIN: You're assuming the only source of information he could have would be that manual?

MS. PAXTON: Right. Now I'm going to lead up to that.

A. I spoke to the developer of that machine before I purchased it. He personally told me there's a homeopathic signal generated from the machine.

Q. Okay. When your nurse went to training, did she bring back any further information to you about this piece of, "this" meaning the homeopathic signal, digital information, et cetera?

[2179] A. No.

Q. No, okay. Did she bring back any information about patients where this should not be used?

A. No.

Q. Conditions –

A. The course was a training course on how to do Electrodermal screening, and I have never used the machine for that.

Q. So is her information, since it was about Electrodermal screening, helpful in any way?

A. It wasn't helpful, but it's nice to have the theory and the knowledge.

Q. Doctor Uberoi had asked you a question, and I didn't quite get clarity and I need to revisit it. She was talking about evidence-based medicine, which we all have learned through our medical training.

Do you have evidence-based medicine that says that the LISTEN device is an efficacious device?

A. An efficacious device in doing what?

Q. To assist you in learning about the patient in terms of allergies.

A. I have evidence from other colleagues who use a device like this, or similar to this.

Q. And is that evidence somewhere before us [2180] today?

A. No.

Q. Is that your only source, then, that this is an –

A. No. Doctor Nambudripad makes homeopathic vials with a machine similar to this, and homeopathic vials work very well in allergy testing.

Q. Now in a machine similar to this, not the LISTEN machine, listening device?

A. I don't know what machine she uses. Maybe she uses a machine, maybe she does not.

Q. So again if it's not the same device that you're currently using, how does that become evidence-based, that it's doing what you need it to do?

A. Well, it would be like a different car, a Ford or a Chevy. It's still a similar machine, it's just made by a different manufacturer.

Q. To do the same thing?

A. Yes.

Q. Thank you, Doctor. That ends my questions.

JUDGE DeBUSSCHERE: Any follow-up questions, Mr. Armstrong?

MR. ARMSTRONG: Yes.

JUDGE DeBUSSCHERE: This is to the

* * * *

[2182] that homeopathy use for treatment?

A. No.

Q. You use that for testing, or –

A. They're used for testing, not treatment, they're used for testing.

Q. The same ones that homeopaths use for treatment, you use that for testing?

A. Correct. We can use homeopathic vials for testing. We can also use samples, like I mentioned before, like a patient may bring in a garage dust sample, house dust sample.

Q. Right. Okay, you just use the homeopathic vials as your allergen?

A. Yes, for testing.

JUDGE DeBUSSCHERE: Mr. Armstrong, follow-up questions by Panel members?

MR. ARMSTRONG: Yes.

* * * *

FURTHER REDIRECT EXAMINATION

BY MR. ARMSTRONG:

Q. Doctor Ames, you mentioned, I'm trying to see if I understand this correctly.

Is it your testimony that the person that sold you the machine, Mr. Clark, didn't give you any information, any documents about this machine and its

* * * *

[1985] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD DAY 1

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

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Renton, Washington
January 13, 2004

REPORTED BY JEAN ERICKSEN, CCR

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* * * *

Patient Name: [redacted]

Date	Weight	Height	Age	B/P	Pulse	Allergies
07/10/01			57	122/80	74r	NKDA

S: F/U

O: Chest: Clear to auscultation
CV: Regular with rate and without murmur
Abd: Benign
Ext: No clubbing, cyanosis or edema

Labs: He had multiple food allergies. Hair analysis showed elevated lead, uranium and a few other heavy metals. He had elevated insulin, CRP-hs, Fibrinogen, cholesterol and LDL. He had low or low optimal A/G ratio, Vitamin B12, folate, DHEA-s, testosterone, pregnenalone, copper, manganese and molybdenum, and WBC's.

A: Hypercholesterolemia
Hyperfibrinogenemia
Hypercoagulation syndrome
Vitamin B12 and folate deficiency
Lead poisoning
heavy metal toxicity
Adrenal fatigue
Multiple food allergies

P: He's going to start 30 sessions of EDTA chelation therapy. I'm going to put him on Testosterone 75mg/g 1 gram qd. Start DHEA 25mg qam, increase weekly by 5 mg to 25mg qam. He's going to be on the low glycemic index diet, followed by the Metabolic typing diet. See pink supplement sheet. I spent 55 minutes with him today.

/s/ [*Signature*]
Geoffrey S. Ames, M.D.

GSA:tem

Patient Name: [redacted]

Date	Weight	Height	Age	B/P	Pulse	Allergies
06/06/01	215	5'10"	57	130/84		NKDA

S: He complains of having chronic fatigue for the last few years, being slightly depressed and having insomnia.

SH: Always a non-smoker, he drinks two drinks in the evening, drinks two cups of coffee a day.

PMH: Right peridiole meningoma removed two years ago. The onset of the symptoms were a grand mal seizure.

Meds: None.

ROS: See intake sheet.

O: HEENT: He has a heavy amount of Hg fillings. Pharynx clear, TM's clear, EOM's full, no thyromegaly, no cervical lymphadenopathy.

Chest:	Clear to auscultations.
CV:	Regular rate, in rhythm, without murmurs.
Abdomen:	Benign.
Extremities:	No clubbing, cyanosis, or edema.

A: Chronic Mercury Poisoning
Hypothyroidism
Adrenal Fatigue
Testosterone Deficiency
Pregnenolone Deficiency
Multiple Mineral Deficiency
Essential Fatty Acid Deficiency
Heavy Metal Toxicity

P: Extensive labs, hair analysis, and basal temperatures.

/s/ [*Signature*]
Geoffrey S. Ames, M.D.

GSA:tem

[2203] proposed treatment?

A. No.

Q. What did he discuss regarding the blood tests?

A. Well, we went pretty much through the cholesterol thing, which I have had elevated cholesterol, and as I remember he was pretty concerned with the Triglyceride level that I had, which I don't understand. That's what I kind of recall. Then some of the minerals and that, like I think I was low in like copper, it seemed I remember, and basically it seemed the focus was on my system was all fouled up, basically.

Q. Did Doctor Ames discuss any allergies detected through your blood test?

A. Yes.

Q. Do you remember that conversation; can you just tell us what you remember?

A. Well, that was the page, we discussed the page in here starting on page 10.

JUDGE DeBUSSCHERE: Exhibit Number 2?

THE WITNESS: Yes, uh-huh.

We went through and he basically said anything with like a six, I was pretty highly allergic to, and egg was the first thing that popped [2204] up there. I just remember egg and mustard are the ones I remember, but he said that was weakening my body also, because of my exposures to these foods.

Q. Did you say it was weakening your body?

A. Uh-huh.

Q. The ones that you remember him discussing was eggs, and what was the other one?

A. Mustard.

Q. Mustard. Have you ever been diagnosed with egg allergy?

A. No, never. I like eggs. I love mustard. I eat tons of mustard.

Q. How about a mustard allergy; have you ever –

A. No.

Q. Have you been tested for allergies before?

A. The last allergy testing that I had done was when I lived in the Tri-Cities before, in 1976 through 1980, and I had severe allergies which are pretty common there in the desert, the typical sort of

blowing dust and pollens and things like that, and I took shots, but I haven't been on those for 24 years.

Q. Did those shots cure you of the allergy?

A. Well, they help relieve the symptoms.

* * * *

[2206] organs to certain, whether they're allergens or chemicals or whatever.

That's the best that I kind of got from it.

Q. Let me see if I understand what you're saying. Did you say electrical magnetic?

A. Uh-huh.

Q. Would that be electromagnetic frequencies, is that the term you're thinking of?

A. That's what I'm thinking of, yeah. Something to do with electrical energy.

Q. That it affects the body in a certain way?

A. Right. If the body is compromised because of food poisoning or a number of things, it actually can change. That's what I understand.

MR. BISHIN: Change what?

THE WITNESS: The electrical conductivity, maybe. There's a difference.

Q. Did he say anything about how the allergy would affect the body?

A. Pardon?

Q. How allergy would affect the body?

A. Yeah, that it would, depending on what it was, it would affect a certain part, and you'd have an allergic sort of weakness from this allergen.

Q. Did Doctor Ames determine, did he explain to [2207] you how he came up with your allergy diagnosis?

A. To the best of my recollection it was based on these lab results.

Q. What about treatment for that egg allergy, did he discuss any types of treatment, possible treatments for you?

A. Yeah. There was, and again I can't remember names, but it was some sort of treatment that would have an influence on this energy sort of level, and the specific like meridians that this energy is focused on, and by changing the, kind of the electrical pathway, it could relieve the symptoms. That's the best I can remember. I'm probably way off, but that was kind of my – I didn't understand it.

Q. Did he discuss a type of treatment or a type of device, do you remember which one?

A. Well, it seems it was kind of bound together. He used the device that I guess supposedly can sense the meridians and simulate the affect of an allergen.

MR. BISHIN: I'll move to strike for lack of foundation, I guess it can sense the –

JUDGE DeBUSSCHERE: I'll sustain the objection on the point that the question is unclear

* * * *

[2223] MR. BISHIN: Yes, Your Honor.

* * * *

cross-examination

BY MR. BISHIN:

Q. So Patient 1 – I have to call you that just to make sure I don't slip – Patient 1, your understanding was that the treatment you received was acupressure; is that right?

A. That's the best I can remember.

Q. The treatment was not from the device; is that correct?

A. My best recollection it was all tied together what was going on, what was treatment, what wasn't.

MR. BISHIN: Your Honor, I want to move to open and publish the deposition of Patient 1.

JUDGE DeBUSSCHERE: For purposes of impeachment?

MR. BISHIN: That's right.

JUDGE DeBUSSCHERE: Do you have the deposition with you?

MR. BISHIN: Excuse me, sir?

JUDGE DeBUSSCHERE: Do you have the deposition with you?

MR. BISHIN: Yes.

* * * *

[2224] MR. ARMSTRONG: I didn't hear what the purpose was, Your Honor.

JUDGE DeBUSSCHERE: For purposes of impeachment.

I have the deposition identified as Patient Number 1 taken on April 3rd, 2003 at 10:30 a.m. in Benson City, Washington. This is the original, and it is so published.

Q. Now your deposition was taken on or about April 3rd, 2003?

A. (Nods head.)

Q. And I took your deposition, is that correct?

A. Yes.

Q. I want to ask you if you were asked these questions and gave these answers. Question, "On the examination we just concluded" – by the way, this is page 90, line 20, Counsel.

MR. ARMSTRONG: Thank you.

Q. Question, "On the examination we just concluded, Patient 1, is it your understanding that

the treatment was, what Doctor Ames did was he asked you to turn over on your back, put pressure on your back, is that what he did?" Answer, "Yeah."

Question, "That was the treatment?" Answer "That's what I understood."

* * * *

[2227] think there was?

A. Yes, probably.

Q. And you testified that you really didn't understand a lot of what Doctor Ames was saying to you?

A. Yes.

Q. Now, you can't point to, you're not claiming, are you, that Doctor Ames caused you any injury, are you?

A. No.

Q. He didn't hurt you in any way, did he?

A. No.

Q. Particularly with respect to this device, you don't know of any injury this device caused you; isn't that correct?

A. No.

Q. You don't know of any injury that the muscle testing caused you; isn't that correct?

A. Yes.

Q. So basically your problem with Doctor Ames is that he sounded – what word did you use – a little obsessed with alternative medicine; is that right?

A. That's fair.

Q. Maybe you felt a lot obsessed?

[2228] A. A lot. I am a little obsessed with it myself.

Q. So he went through a large range of alternative forms of health care and ideas, and did it in a way that you thought was kind of intense; is that correct?

A. Yes.

Q. As I understand your testimony at the deposition, when you wrote to the medical Commission you didn't really consider yourself as complaining about Doctor Ames; isn't that correct?

A. Yes.

Q. You thought basically that you were disturbed by the experience you had with him, and you wanted them to know about it; isn't that correct?

A. Yes, I felt uncomfortable, to where I wanted to get some answers. I certainly didn't feel like it applied to myself, but the whole scenario, what happened was what I'd say I think this should be looked at, and that was basic, but I had no real, quote, complaint.

Q. You wanted them to look at it, and they have more expertise in investigating and looking into issues like this, they're doctors, let them see what it is. Basically you were just informing them,

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[2243] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: GEOFFREY S. AMES, M.D., License No. MD 00026961, Respondent.	)	Docket No. 02-06-A-1012MD

TRANSCRIPT OF PROCEEDINGS
DAY 2

(Filed Oct. 15, 2004)

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and it wasn't asked in Cross.

MR. ARMSTRONG: My notes are, as a matter of, the last thing we talked about before the fillings versus toxicity was, counsel asked him about Dr. Ames's reliance on the machine. And his answer was Dr. Ames could do this in other ways. I'm asking him about, to clarify that statement: Do what in other ways? So that's essentially my question, and it was the very last that we talked about: Counsel is putting on the record that it doesn't exist, and I'm saying it's the very last thing that did exist.

MR. BISHIN: Your Honor, this was brought out on Direct Examination, it was covered in Direct Examination.

MR. ARMSTRONG: And it was covered on Cross-Examination. That's what I'm recalling in my notes. That's what I wrote down.

JUDGE DeBUSSCHERE: Prior to the questions asked about mercury fillings on Cross-Examination, there was a series of questions asked about taking seriously the form that he completed prior to seeing the respondent on June 6, 2001. There was questions asked about his comments of what Dr. Ames stated he could or could not do with –

MR. ARMSTRONG: That's exactly what I'm

* * * *

[2269] ***Patient 1 – By Ms. Paxton***

A Yes.

Q Did that actually occur?

A Did what –

Q Were you cured of your egg allergy?

A Well, I don't know. I still eat them, but I haven't reacted.

Q Did Dr. Ames talk to you about, when you talk about an allergy, we talk about, you know, congestion, hives, maybe, closing of the throat, whatever

the extent of that allergy might be. What were your symptoms regarding allergies?

A My only symptoms that I knew of, as I stated before, were linked to, like, hay fever. I have never been diagnosed with any food allergies.

Q When you say "hay fever," what do you mean?

A Pollen, blowing dust, the tree pollens.

Q What does your body do, when that's occurring?

A Respiratory difficulties, plugged up, sinus drainage, eye itch.

Q So based on what you described as your allergy reaction, your body's reaction to pollen or eggs or whatever, when you have eaten eggs after your treatment, what's been your body's reaction?

A No reaction.

Q No reaction?

* * * *

[2271] ***Patient 1 – By Ms. Paxton***

with the LISTEN device and the outcome there versus, at some point, Dr. Ames said he could figure out the same problem or the same allergies not using the device. Can you clarify that piece, for me? Do you remember that discussion earlier?

A Yes.

Q Okay.

A It just goes back to the question I had asked as to why he had wrapped the probe in a tissue paper.

Q Okay.

A He was hesitant. And that's when he said to the effect he didn't need the machine anymore and that he could, whatever this energy meridian, electromagnetic thing is, that he could do that, he's done it so much. That he could do what the machine did. Again, not myself fully understanding what machine was doing or supposed to be doing, but that was the reason he gave for wrapping the probe in the tissue the last time.

Q So your understanding of wrapping the probe was that – What is your understanding of wrapping the probe?

A My understanding of the conversation we had was, by wrapping the probe, he wasn't using the machine, he was doing it himself. That was my understanding of what he meant. There was nothing talked about sweat in my hand or anything like that. The context was, as it came [2272] across to me and I interpreted it, is that he didn't use the machine that time.

Q But he still had you hold the probe?

A Yes.

Q Did you wonder why you just didn't put the probe down?

A No.

MS. PAXTON: I have no more questions. Thank you.

JUDGE DeBUSSCHERE: Mr. Tennis, did you have any questions? You passed on the first set.

MR. TENNIS: No, I think I'm fine. Thank you.

JUDGE DeBUSSCHERE: Dr. Uberoi?

Patient 1 –
BY DR. UBEROI:

EXAMINATION

BY DR. UBEROI:

Q Mr. Patient 1, on your second visit, you don't remember hearing the word kinesinyol –

MR. BISHIN: Which word?

Q (By Dr. Uberoi) Kinesiology.

MR. BISHIN: Which word was that? I'm sorry. I didn't hear.

DR. UBEROI: On visit two, I said, did he hear the art of kinesiology or anything.

A I don't recall hearing that.

* * * *

[2274] ***Patient 1 – Recross (Bishin)***

The purpose of counsel's question, he's made several attempts to quash any questions on kelation, and now he wants to go into it to clarify. I don't know what purpose, since he is making an argument that it's not relevant, it's not part of the statement of charges, shouldn't be considered, shouldn't even be asked by the panel, shouldn't be asked by me. Now, he wants to go into it. There would be no purpose, if they were not going to make a determination on this topic or the issue that he should go into that area.

MR. BISHIN: That's fine, so long as we strike all the testimony and questions about kelation in this proceeding.

JUDGE DeBUSSCHERE: I won't strike the testimony, but I will grant the department's objection. So the objection is sustained, with regards to kelation therapy.

MR. BISHIN: That's fine. That's the same effect.

Q (By Mr. Bishin) Let me ask you this. You were asked about whether you were cured of your allergy to eggs and about symptoms. Yesterday, we went over a bunch of symptoms that you had. We don't know what they are symptoms of; isn't that right? You don't know what they are symptoms of, why you were tired, why you had the [2275] fatigue. Those were symptoms, you understand that?

A Right.

Q Now, I think you almost cleared this up. I want to make sure you did. It wasn't Dr. Ames who said that he wrapped the paper because he wanted to do the, he wanted to do the process by himself without the machine. That was your interpretation of what he was doing because he said that he could do it without the machine; isn't that correct?

A Yes.

MR. BISHIN: That's all. Thank you.

JUDGE DeBUSSCHERE: All right. That's all the questions asked of this witness.

Mr. Armstrong, is there any reason why this witness cannot be excused so he can leave the hearing? Do you wish to keep him here?

MR. ARMSTRONG: No, no. I'd like him to be released.

JUDGE DeBUSSCHERE: Mr. Bishin, do you have any reason why.

MR. BISHIN: No objection. And I thank the witness.

JUDGE DeBUSSCHERE: Thank you very much for coming in. I know it was difficult for you to make it here. You are excused, and you can leave. Thank you

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[2243] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of:	)	Docket No. 02-06-A-1012MD
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[2283] ***Sherman – Direct (Armstrong)***

JUDGE DeBUSSCHERE: Thank you. Your witness, Mr. Armstrong.

MR. ARMSTRONG: Thank you.

DIRECT EXAMINATION

BY MR. ARMSTRONG:

Q Good morning, Dr. Sherman. I have here your CV and its extensive credentials.

MR. BISHIN: I object to the characterization.

JUDGE DeBUSSCHERE: Objection overruled. Go ahead, Mr. Armstrong.

Q (By Mr. Armstrong) I have your CV in front of me. I'd like to just have you talk a little bit about your background and history. I won't go into extensive because we have this here. And you've already been ruled as an expert by the Court. So don't need to establish anything, other than you are an expert for this case.

Could you just tell us a little bit about your educational training. Just give us a summary of your background, and then go into your work history.

A I have a doctoral degree, a Ph.D., not M.D. in a combination of biology and psychology, which at this time would be called psychophysiology. The term simply [2284] wasn't used in the dark ages. And I've been working in that field for nearly 30 years.

Most of my professional experience is either with the Veterans Administration for a short time, and almost the entire remaining time with the United States Army. And throughout that period, I was always doing research and clinical work in

psychophysiology, which is, essentially, relationships between the mind and the body. The mind's actions influence the body, how the bodies influence the mind, et cetera.

I've got over 100 publications on basic research and clinical studies in that area. Also, chapters especially on instrumentation and how the instruments work within the field of psychophysiology. And within psychophysiology, my area for well over 20 years, has been biofeedback. That's the area of the field that I'm most expert in.

Q (By Mr. Armstrong) Dr. Sherman, do you have any teaching assignments in your history?

A Yes. Throughout my military career, I was assigned to teach research techniques and analysis to orthopedic residents and sometimes psychiatry residents and others. But basically, orthopedic residents. I've taught at the undergraduate level, on and off, for most of my career. Then, within the last five years, I've been director of

* * * *

[2290] done for well over 50 years. We can record how much someone is breathing in and out, we can record their muscle tension, near-surface blood flow, parameters like that, EEG.

When that's recorded in real time, and those recordings are shown to a patient, either on a computer monitor, say, or a dial, or a sound that would change as the physiology changes, that's biofeedback.

So you are making a standard psychophysiological recording using standard psychophysiological recording equipment, as would be done in any major medical center, in a sleep lab or a respiration lab or rehabilitation medicine clinic.

The part that's biofeedback is that the patient can see the display or hear the display, so that the patient is aware of the level at which a physiological parameter is functioning at that very second. They can use that knowledge within a therapeutic context to say, oh, that's wrong, or that's right. Then, attempt to change the way the parameter is functioning to a more-correct level. So that's what biofeedback is.

Q (By Mr. Armstrong) You've mentioned equipment. Are there different devices that you can use for biofeedback?

A Yes. Any way that you can objectively record what a [2291] physiological parameter is doing in today's environment, those are virtually all electronic devices. The simplest device, however, would be a mirror. If you had somebody who had a problem with their gait and they were walking back and forth in front of a mirror, they would be getting feedback using the mirror of what they were doing.

Normally, what we're discussing, however, is an electronic device that can pick up and amplify a signal that's too small for either the therapist or the client to perceive, at least, initially, without help of the amplification.

So in other words, one of the powers of psychophysiological reporting is that you can amplify a very signal so it's large enough so that the therapist and the patient can see it and tell what it's doing very, very accurately.

So for instance, if a physical therapist were to touch somebody's bicep and try to judge how tense it was, that wouldn't be particularly objective because from, say, session one to another session a week later, they forget, really, what their feelings were. And also, some of the most important changes in tension are too small for another person to feel from the surface of the skin. We just aren't built with that sensitivity. [2292] While an electronic amplifier can ascertain just what the level is, and you can compare a recording on week one with a recording on week two and know that it's the same, within reasonable limits of accuracy.

Q Dr. Sherman, have you used any electronic devices in conducting biofeedback?

A Yes.

Q Could you describe what was one looks like?

A A modern biofeedback device is a computer-based device. There's a small box that's attached to the computer that takes in the signals.

So picture leads taped to a patient's forehead. Say, if we were going to record muscle tension from the facial area, there would be some leads taped to the forehead, wires would be running from the leads

to a very small box. These, the sensors are picking up ionic potentials. I'm not trying to talk in gobbledygook. It's the electricity coming out of the skin that the muscles make. So the sensory would be picking up the muscle tension, and it would go to a small box which has two functions. One function is to convert the signals from the constantly changing signal that's coming out of your skin to a digitized signal that the computer can pick up. An analog to digital converter is frequently in that box. Also, an amplifier in that box that makes [2293] the signal large enough for the computer to work with.

The other major component in that box is called an optical isolator. It's an air space. No electricity goes across that air space from the direction of the sensors to the machine or from the machine back across to the sensors. It works normally with an infrared signal, just like a TV's remote control, puts out a little varying signal. This is a safety device, make sure that nothing can get from the computer to the patient. So that signal coming in is varying like this, and it makes a light wave vary. The light wave goes across an air space. Then, you have an electronic amplifier on the other side. So it's a one-way process.

That's basically what's in this small box that simply plugs into the computer's port. There's no special board in the computer. The computer itself contains all the software you need to adjust the signals so that it's a good learning experience for the patient.

If somebody was watching a muscle-tension signal just bouncing up and down like this, you might not –

THE WITNESS: This might be difficult for the court reporter.

Q If you could, Dr. Sherman –

A It's a varying signal going vertically up and down rapidly. That kind of signal will be very difficult to [2294] learn from. So the signal is changed by software in the computer so it's an intelligible learning signal. That's basically it.

So again, this is within a therapeutic milieu. A patient could stare at the screen forever and not learn anything from it particularly, a therapist saying what that is, what that has to do with their condition.

Q So Doctor, you need training in order to conduct biofeedback properly?

A Yes.

Q I want to make sure I understand what you were saying about the signals. Would you agree that, interpreting what you've said correctly, I take it from your testimony that the biofeedback device, one that you know of, that's been approved and to be used in industry, in your scientific circles and your community, it takes signals from the body. Could I use the word "energy" from the body?

A Yes.

Q It takes energy from the body, and it processes it and puts it into some type of display that you can see? Correct, so far?

A With one exception, yes.

Q Okay. And then, the optical isolator, one of the purposes is to make sure that no energy goes back to the [2295] person's body so there's no complete loop?

A With one exception, yes.

Q Okay.

A The one exception is, if you are recording sweating, sweating is an excellent indicator of autonomic arousal, the idea that you are getting nervous, and just how tense are you. Sweating is recorded by running a tiny current across the surface of the skin, from one sensor to another. Your sweat is, essentially, salt water, for purposes of this discussion. Salt water conducts electricity. So the more you are sweating, the easier it is for that tiny current to go across the skin. So there's two sensors, any two places. Maybe one finger to one finger. You simply record how difficult it is for this tiny current to get across the skin.

Now, I say "a tiny current," I literally mean that. This is in microamperes. It's not enough for anybody to be able to feel it or for it to cause a problem in the body. If you try to light a light bulb with that, nothing would happen. This is a tiny amount. So that's the one exception.

Q Doctor, in your understanding, do all biofeedback devices have this safety?

A The optical isolator?

Q Yes. So that energy can be read from the body but no [2296] energy returns back to the body, do they all have that?

A They either have that or something exactly like it, very, very similar.

Q And is the purpose the same?

A Yes. It's all the same is that if there were to be a fault in the wiring, a ground fault, where somebody could get a shock, that couldn't happen. All these machines have many safety devices. They normally have ground-fault interrupters, just like in your bathroom.

Q Okay.

A The whole idea is to make it very, very safe for the patient.

Q Thank you, Doctor. The subject of this hearing is Dr. Ames's practice with Patient 1. And in the statement of charges, the department is alleging that he used an electronic device.

I want to ask you this question here. And the device is to your left.

A This or this?

Q That?

A This one?

Q Yes.

A I'm pointing to, maybe, a brass tube on a rectangle.

Q Could you just describe what you see next to you?

A A brass tube on what appears to be a brass rectangle, [2297] and it's got a computer-interface cable coming out of the brass rectangle. The tube, the brass-looking tube, maybe four inches long, is connected by some sort of cable to the base unit containing the brass plate.

Q Doctor, if I were to say that this device – and for our purposes, we'll be calling it the LISTEN device. That's L-I-S-T-E-N.

Have you ever heard of that device before?

A In a previous hearing, I did.

MR. BISHIN: I'll object. He's asked him to describe a part of this device. Now, he wants to describe the part as the LISTEN. I want to make sure that the record reflects that this is misleading and inaccurate.

A I don't know what any of this is, if that's what you are asking.

JUDGE DeBUSSCHERE: Objection sustained.

Q (By Mr. Armstrong) I'm not asking –

JUDGE DeBUSSCHERE: The record shows that the device, the LISTEN device, is not just the rectangle and the brass tube, but the other equipment here on the table.

So I'll sustain the objection on that assumption.

Q (By Mr. Armstrong) For the record, Doctor, could you describe all the items that are just to your left?

[2298] A Seeing another rectangle called a line master. I don't know what that is either. And there's what appears to be a standard. PC computer and, I think, a monitor, and there's a keyboard.

Q That's not part of it.

A Oh, this isn't part of it?

Q No.

A Okay. There's some other thing on the table that I don't know what that is.

Q So essentially, Doctor, could I recharacterize what you just described as a computer setup with a keyboard, a monitor and a tower with a black rectangular box with a cylinder hooked to it and another gray rectangle hooked to –

A Yes. And the base unit, the rectangle containing the brass plate is, well, apparently attached to the back of the computer.

Q I'll be referring to that device as the LISTEN device, just for simplicity?

MR. BISHIN: You mean, the entire configuration.

Q (By Mr. Armstrong) The entire configuration that you just observed and described as the LISTEN device.

Now, my question is, have you ever heard of the LISTEN device before this proceeding?

[2299] A Before the deposition and before you contacted me, I had never heard of it.

Q I want to get back to how a biofeedback device works. I want to deal with the energy flow and how it works.

If I was to tell you that this LISTEN device, just for argument purposes, if I describe the LISTEN device as a device that reads energy from the body and then sends energy back to the body, would that be a biofeedback device, based on your understanding and, expertise in biofeedback.

A The energy going into the body is more than informational?

Q No. I'm saying, if I was to say that this machine has a cylinder as what you just described and that is held by a person, a patient –

A Yes.

Q – and it reads energy from their body, electrical current, signal –

A Whatever.

Q And it goes into the machine, but the machine also sends energy back from the machine back to the body.

A The reason I'm asking you to be very specific is that biofeedback could also be done by an electrical vibrator. Many biofeedback devices are very tiny so that you wouldn't believe that someone was wearing them.

* * * *

[2316] I'll grant the motion, his opinion, off-label use, that's a conclusion of law.

Q (By Mr. Armstrong) Dr. Sherman, let me move to another area dealing specifically with the biofeedback machine.

Do you use one currently in your practice at Madigan?

A Yes.

Q You are familiar with what they look like, how they operate. Are you familiar with the labeling of a biofeedback machine that you use?

A Yes.

Q Just a second. Follow up on that. Could you simply tell us what the labeling is on biofeedback machine that you use? What's it labeled for?

MR. BISHIN: Object on the grounds of relevance.

JUDGE DeBUSSCHERE: Overruled. Go ahead.

A I use two different – well, three different devices. They each have different labels.

Q (By Mr. Armstrong) Give me one. What's the label for?

A Safe and effective for the treatment of anxiety and muscular rehabilitation.

Q In your experience with biofeedback machines, do they have the capability of diagnosing ailments? Can a [2317] biofeedback machine diagnose an ailment in a human?

A Well, the information that you get from the machine can be used with your clinical knowledge to make a diagnosis. If you LISTEN to a stethoscope, the stethoscope is not telling you what's wrong with the patient. You are using information from the stethoscope.

That's the same thing with a biofeedback machine. It can tell you that the muscles are not functioning normally, for example. And then you could say, all right, this is abnormal under these

circumstances. Then, you could go ahead and make a diagnosis within your credentials at your institution.

Q That would be the professional making the diagnosis. I'm asking, can the machine, the device itself, make a diagnosis of any illness?

A You mean, does something pop up on the screen and say this person has –

Q Yes, that's what I'm asking.

A No.

Q Are you aware of any medical device –

A I'm not competent to say that.

Q You are not aware of any?

MR. BISHIN: We don't know even know what the question is yet, but you know the question.

[2318] THE WITNESS: That's true. I was asked if any medical device can do that. I don't know.

Q (By Mr. Armstrong) Are you aware of any medical device that can do that?

A No.

Q Are you aware of any biofeedback machines that can treat allergies.

A No.

Q Dr. Sherman, are you aware of – Do you know what a galvanic skin device is?

A That's very general. A galvanic skin recorder? Is that what you are asking me about?

Q Yes. What is that?

A What they are talking is recording sweating from the surface of the skin. There are several traditional measures. One is just how much you normally sweat. That would be called galvanic skin level. Then, there are responses where, let's say you are just sitting there, and somebody comes up behind you and claps suddenly so you are startled, then there will be a, squire out some sweat so that you would see a change in the recording. That would be the galvanic skin response.

And as I testified to earlier, you would have, generally, two sensors on the hand and you'd be [2319] recording resistance to an electrical current going across the skin. And again, that resistance is dependent on how much saltwater is on your hand.

Q Based on your knowledge, does galvanic skin recorders have ability to diagnose-ailments?

A Within the context of psychophysiology, no.

Q How about cure any ailment?

A None of the devices that I am professionally familiar with do more than provide information to a therapist and patient which they can use together to enhance the person's control. And if the parameter that we're talking about is behaving abnormally and causing a disorder and if correcting that disorder,

correcting the way the physiological parameter is functioning corrects disorder, then the patient who successfully learns to control the abnormal functioning is very likely to get better.

Does that answer your question?

Q Yes, it does.

Are galvanic skin recorders the same as biofeedback devices or are they different?

A When you say biofeedback device, I believe what you are really talking about is two different stages. One is recording, psychophysiological recording. Showing the patient the recording is the biofeedback.

[2320] Q Okay.

A So we're talking about a psychophysiological recording device.

There are many dozens of different devices on the market that can record how much you are sweating, including devices you can buy at places like Radio Shack or, at least, you could until a few days ago. I assume they are still on the market. Trying to be careful here.

Q Yes, I understand.

A They simply record how much you are sweating. And they are used for all kinds of different purposes. They are not only used for clinical

purposes, they are used as part of games and whatnot. So there are lots of different recorders.

Q Just have a few more questions. Do you have an understanding of the term "substantial equivalent" as defined by the FDA?

MR. BISHIN: Objection, irrelevant.

JUDGE DeBUSSCHERE: Calls for a conclusion of law, what the FDA uses the term "substantial equivalent."

MR. ARMSTRONG: Well, Your Honor, I'm asking the question because testimony has been given that he has experience with the FDA and their process of

* * * *

[2326] ***Sherman – Cross (Bishin)***

there?

A Those people are basically psychophysiologists.

Q That is what they do?

A Yes. Almost all of them are psychophysiologists. You are talking about Benson?

Q Right.

A Benson has one team at Harvard. There are a number of other teams at Harvard. As is true with any academics, none of them agree with each other. They are all doing psychophysiology.

Q Let me ask you this question. I'd like you to describe a little bit more clearly what it is that biofeedback actually does. You've told us that a biofeedback machine records and displays information; is that correct?

A Yes.

Q Is that part of it?

A That's almost all of it.

Q Okay. But biofeedback is more than that, isn't it? It's more than recording and displaying?

MR. ARMSTRONG: Objection, Your Honor, asked and answered.

JUDGE DeBUSSCHERE: Overruled.

Q (By Mr. Bishin) Biofeedback is more than that, isn't it?

[2327] A No.

Q Isn't there a –

MR. ARMSTRONG: Objection. Again, asked and answered, definitely.

JUDGE DeBUSSCHERE: It was raised on Direct about what biofeedback is. He has an opportunity to cross-examine that. It's not asked and answered. It's been asked by you. Now, it's opportunity for Cross to be asked on Cross.

MR. ARMSTRONG: I understand, Your Honor.

JUDGE DeBUSSCHERE: It's the area. He's asking about the area that you inquired on Direct.

MR. ARMSTRONG: I'm not objecting to that. I'm objecting to, he asked the question, and the witness answered. And. he asked it again, and the witness answered. The witness has already answered. I'm not sure what answer counsel is looking for, but he gave the answer to the question. He didn't like it, so he asked the same question again, to be more emphatic. I'm saying that the question –

JUDGE DeBUSSCHERE: I see what you are saying, that immediate question.

Mr. Armstrong is objecting that you asked two questions, same question at the same time. So please rephrase your second question.

[2328] Q (By Mr. Bishin) My question is, isn't there more to the biofeedback process than merely the recording of some kind of physiological parameter and the display of that parameter, isn't there, in fact, a role for the subject, the person whose parameter is being recorded and displayed in the biofeedback process?

JUDGE DeBUSSCHERE: Go ahead and answer that, Dr. Sherman.

A Yes.

Q (By Mr. Bishin) You used the word "control" before. Remember that? You wanted to somehow effect the subject's control; is that correct?

A Yes.

Q What did you mean by that?

A When you are asking about the biofeedback process as opposed to a biofeedback device, a subject, be it a school child, learning to concentrate better, a patient, an athlete, whatever, they are being coached by someone who is knowledgeable about physiology and physiological responses to use the information for some purpose so they are learning to recognize what their body is doing and appropriate circumstances to control it. So that's part of a loop. And then, presumably, recording will change, if they successfully control it. So yes, that's part of the loop. It's, of course, not part of the, the [2329] machine is not doing that –

Q Then, if I understand the clarification, what you are saying is that biofeedback, that's a word –

A Right.

Q – and that's a process?

A Yes.

Q A biofeedback device is a device, as I understand your testimony, which is used in the process of biofeedback?

A Yes.

Q But the biofeedback device doesn't do everything that occurs in the biofeedback process?

A That is correct.

Q So in the biofeedback process, there's an individual whose psychological and physiological parameters are being recorded and displayed who is going to use, supposed to use that information to change those parameters if the parameters are not satisfactory from the point of view of that person's comfort or health other whatever it is; is that correct?

A Yes.

Q Now, how does the individual use that information in the biofeedback process?

A How do they use it?

Q Yes. Let me put it another way.

MR. ARMSTRONG: Objection, vague.

[2330] JUDGE DeBUSSCHERE: Sustained.

MR. BISHIN: I'll withdraw the question.

Q (By Mr. Bishin) My point is this. These biofeedback devices are being used, are they not, to achieve changes in human beings; isn't that correct?

A They are part of the process, yes.

Q Their function is to change people in some way; isn't that correct?

A No.

Q What is their function?

A Their function is to provide information, and the patient and the therapist or coach that's with them can work together to use that information to change it. The device isn't having any direct effect on the patient.

Q No, it's the patient who's doing the changing, isn't it?

A Right.

Q It's the patient, sometimes with the aid of a trainer –

A That's right.

Q – who's doing changing?

A Yes.

Q But the device would not be sold in stores or markets or wherever it is, unless it made it possible for people to get the information so they could change those parameters; isn't that correct?

A Yes, which is very different than what you said before. [2331] The device isn't doing the changing, the device is providing information.

Q I wasn't saying that. My question is, this is your field?

A Right.

Q Your field isn't simply designing these devices and showing people how to use them and display them. Your field is also dealing with the phenomenon of people using the information to change their bodies in some way?

A Yes.

Q That's part of your field. That's a part of psychophysiology, is it not?

A Yes.

Q That's what I was getting at, when I was asking about psychophysiology.

Now, is it fair to say, then, that, in your field, you study the phenomenon, among other things, how the mind can change the body?

A Of course.

Q That's part of what you mean by mind-body relationships; isn't that correct?

A Yes, it is.

Q When that individual changes, when an individual gets that information, an individual doesn't change his or [2332] her body by applying a hot compress or a cold compress or some instrument or anything like that. That person, through the use of his or her mind, makes the change; isn't that correct?

A Yes.

Q Now, the question becomes, how can a human being change their body simply through the use of their mind? How does psychophysiology justify that?

A You mean, what's the evidence that people can do that?

Q Yes. Not the evidence that they can do it. We know they do it. You wouldn't have a biofeedback industry if they couldn't do it. The question is, you are a scholar and a scientist. You job is partially, is it not, to explain how that can happen?

MR. ARMSTRONG: Objection, Your Honor, relevance. Counsel has asked the question, but the relevance, how is that going to help the panel determine the charges in this case? We can do an educational seminar on a lot of topics, and I'll learn a lot as we speak, but that's not relevant, and I see a waste of time.

MR. BISHIN: Well, part of the underlying prejudice of the government's entire case here is the notion that through some nonmaterial agency what you cannot perceive that Dr. Ames is achieving various [2333] results, in other alternatives, he's achieving various results. Here, he's brought on somebody who's a psychophysiologist, and what I'm trying to indicate here is that this particular person who is a scientist on biofeedback machines is a person who himself necessarily gives some authority to the notion that mind can change the body. In this particular case, it's usually the mind of the individual changing his own body. But nevertheless, it's the mind changing the

body. It's a nonmaterial phenomenon that's going on here. That's why I'm raising this point in the course of this testimony. That's why it's relevant.

MR. ARMSTRONG: May I speak before your ruling?

JUDGE DeBUSSCHERE: Yes.

MR. ARMSTRONG: I renew my objection because the Court has limited this hearing to the treatment of allergies regardless of what the mind and body can do or not do, whether it's proved here in this hearing or is not. If it doesn't have anything to do with the treatment of allergy by a licensed physician is not relevant, and it's a waste of time.

MR. BISHIN: He asked about biofeedback machines generally.

JUDGE DeBUSSCHERE: Overruled. Questions

* * * *

[2338] we understand what you are talking about.

The coach, as I understand, you gave a number of different coaching examples in the course of that answer. I'll take one. You are saying a coach is watching what you are doing, watching how you are doing sit-ups, and telling you that's not the way you should be doing it. Now, the coach there is doing two things, is he not – or she not. First, the coach is, in effect, serving as sort of a monitor and telling you what you are doing. So it's, in effect, a display and a

recorder of what you are doing. So like this device over here, insofar as it provides that kind of –

A That's exactly right. They are biofeedback.

Q They are the device –

A Yes.

Q – the coach becomes the device in a sense?

A Absolutely.

Q But then the coach does more than that. The coach tells you how to change it and gives you information. The coach gives you information about where you should be. All that could be done on a computer, too, couldn't it? A computer could tell you what you are doing, and it could also tell you what you should be doing by simply displaying information about, assuming that there was information available on this particular subject, it [2339] could display information about – Let's say your heart is beating graphically like this, and the computer shows that. The computer will also show you, based on whatever information you put into the computer as to who you are and how old you are and what you weigh, et cetera, it can also tell you what the graph should show right over there. It can show you that. And that's being like a coach in this particular situation. This is as it should be. Then, you can use that information to change your heart, the graph. I mean, in principal, assuming that you can have that effect on a autonomic nervous process like that. Which biofeedback seems to assume, doesn't it?

A It's been proven.

Q It's been proven, right.

So the coach is playing a role that could be played by a computer that was properly programmed; is that correct?

A Theoretically, if such a program existed, yes, you could do it.

Q All right. Now, would that be a biofeedback machine, if it did that?

A It would be a biofeedback machine and now also another machine. It would be an expert system. So it would be two different processes within the same machine, but it

* * * *

[2345] All right. You are aware that there are studies indicating that even prayer can have physiological change?

A Absolutely, absolutely. They know exactly how it works now.

Q But it does happen?

A Absolutely.

MR. BISHIN: No further questions.

JUDGE DeBUSSCHERE: Redirect, Mr. Armstrong?

MR. ARMSTRONG: I just have one question and allow the panel to go, after that.

REDIRECT EXAMINATION

BY MR. ARMSTRONG:

Q My one question, if you can believe it, is when counsel was asking you about the biofeedback machine, that it can at as a coach, your answer was, theoretically, the machine can actually, can substitute as a coach?

A That's not what I said, please.

Q Okay.

A I said that you would have to add another process. It would simply be inside the same machine because computers can run two programs at the same time. That's not biofeedback. Now, you are going to another process

* * * *

[2347] A Yes.

Q All right. Could you tell me about that?

A Not generated we a computer purposely.

Q All right.

A A computer, just like any other electronic device, produce fields, produce electrical fields.

Q Sure.

A People who work around gigantic magnets have all kinds of psychological and physiological changes that are very, very well documented. Not necessarily all deleterious. Sometimes your mental status changes when you are around a very, very large magnet for a prolonged period of time. People are affected by numerous magnetic fields that are generated by all kinds of things.

Am I answering what you are asking?

Q Yes, I think you are, in some ways.

Does your field, psychophysiology, look at, have any understanding of the practice of acupuncture or acupressure?

A My area of expertise doesn't extend to that. There, are numerous psychophysiologists who do study acupressure and acupuncture, but I'm not one of them.

Q Are you aware of any conclusions in the literature?

A I would refer you to the National Institutes of Health,

* * * *

Supreme Court, U.S.
FILED

No. 09-734

DEC 17 2009

OFFICE OF THE CLERK

In The

Supreme Court of the United States

GEOFFREY S. AMES, M.D.,

Petitioner,

vs.

WASHINGTON STATE HEALTH DEPARTMENT
MEDICAL QUALITY HEALTH ASSURANCE COMMN.,

Respondent.

On Petition For Writ Of Certiorari To The Supreme Court Of The State Of Washington

APPENDIX, PART TWO
PETITION FOR A WRIT OF CERTIORARI

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[2243] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In the Matter of the License to Practice as a Physician and Surgeon of: GEOFFREY S. AMES, M.D., License No. MD 00026961, Respondent.	Docket No. 02-06-A-1012MD

TRANSCRIPT OF PROCEEDINGS
DAY 2

(Filed Oct. 15, 2004)

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* * * *

[2386] Ms. Paxton. They are hearing this case. I'm presiding over the hearing. There is a court reporter recording this proceeding. Mr. Keith Armstrong is the assistant attorney general, and he's representing the Department of Health. Mr. William Bishin, Attorney at Law, is here, representing Dr. Ames, who is present.

You've been designated to testify as a witness, I will ask the court reporter to swear you in at this time.

NEIL OGDEN,

having been first duly sworn by the Notary, testified as follows:

JUDGE DeBUSSCHERE: One requirement that I ask of you, Mr. Ogden – this is Health Law Judge Art DeBusschere – is that you are testifying as a fact witness. And I'd ask that – Of course, I understand you are employed with the FDA. And if you have documents there when you testify, if you are referring a document, we'd ask that you identify that document prior to your testimony, okay?

THE WITNESS: Yes.

JUDGE DeBUSSCHERE: Do you understand that requirement?

THE WITNESS: I do.

JUDGE DeBUSSCHERE: Can you hear me okay?

[2387] THE WITNESS: Yes.

JUDGE DeBUSSCHERE: I ask, if you can speak up just a little bit, too, so we can hear you. We have you on a speaker phone.

THE WITNESS: Yes, I'm on a speakerphone as well, because with me is Mr. Carl Turner, who is an attorney for the Commissioner's Office.

JUDGE DeBUSSCHERE: Will he be there, is he there to listen or is he going to be advising you while you testify?

MR. TURNER: I'm primarily here to listen, Your Honor.

JUDGE DeBUSSCHERE: All right. Well, Mr. Turner, if you do say something, I would ask that you alert us what you are doing, okay?

MR. TURNER: I will.

JUDGE DeBUSSCHERE: Thank you.

Mr. Armstrong – Let's see. One other thing. Mr. Ogden, I understand you have to leave at 5:30 your time; is that correct?

THE WITNESS: Yes, it is.

JUDGE DeBUSSCHERE: What time do you have there?

THE WITNESS: 4:25.

JUDGE DeBUSSCHERE: You are at 4:25?

[2388] THE WITNESS: Approximately.

JUDGE DeBUSSCHERE: So it looks like you have about an hour and five minutes available to testify?

THE WITNESS: That would be correct.

JUDGE DeBUSSCHERE: Because of that, I'm going to limit the parties to how much time they have. So I will give Mr. Armstrong 20 minutes for direct; Mr. Bishin, 20 minutes for cross. Then, the panel members may want to ask you some questions, and I give them 20 minutes to ask you questions as well.

So go ahead, Mr. Armstrong.

MR. BISHIN: Just one moment. I want to make sure it's clear on the record that I object to this procedure, insofar as my right to cross-examine, my client's right to cross-examine has been curtailed.

JUDGE DeBUSSCHERE: Yes. Your objection is on the record. Thank you.

Go ahead, Mr. Armstrong.

DIRECT EXAMINATION

BY MR. ARMSTRONG:

Q Good afternoon, Mr. Ogden. Can you hear me okay?

A Uh, fairly well.

Q I'll try to speak up.

* * * *

[2399] cross-examination. Mr. Bishin?

CROSS-EXAMINATION

BY MR. BISHIN:

Q Mr. Ogden, good afternoon.

A Good afternoon.

Q First of all, Mr. Ogden, you don't have any personal knowledge of the LISTEN device that was purchased by Dr. Jeffrey Ames, do you?

A That's correct.

Q You don't know what labeling that device had on it; isn't that correct?

A That's correct.

Q And you don't know the specifications that it has; isn't that correct?

A That's correct.

Q Now, let's go talk about the Digital Conductance Meter for a Moment. You just testified unequivocally that if there were changes made to the LISTEN device, it would require another premarket notification and clearance, or did I misunderstand what you testified to?

A That's correct.

Q You are saying that any changes to a device that has been cleared requires a new clearance?

MR. ARMSTRONG: Asked and answered, [2400] objection.

JUDGE DeBUSSCHERE: Overruled.

A No, that's not what I'm saying. You could make minor changes to a device by changing the screws on the box, change some resistors, perhaps, in their circuits to make it perform in the same manner but more efficiently, and still not require a new premarket notification.

Typically, the trigger for acquiring a new premarket notification is you've changed the performance of the device in such a way that it now is outside the performance range that was cleared.

Q (By Mr. Bishin) Wait a minute. Now, Mr. Ogden, that isn't what the FDA says in its published documents, is it?

MR. ARMSTRONG: Objection. Your Honor, he is asking the witness for a legal conclusion, and you've already ruled that's not going to be allowed in this case.

JUDGE DeBUSSCHERE: Overruled.

Q (By Mr. Bishin) That's not what the FDA says in its published documents, is it?

MR. ARMSTRONG: Objection, again, Your Honor.

JUDGE DeBUSSCHERE: Overruled.

MR. ARMSTRONG: Which document that he's [2401] referring to? Web site, physical documents, legal documents from the Office of Compliance? It's vague. We don't know which documents he's referring to. The FDA is a giant organization. They have millions of pieces of paper. Which document is Mr. Bishin referring to in making this statement?

JUDGE DeBUSSCHERE: Overruled.

Do you remember the question, Mr. Ogden?

A Please repeat it.

Q (By Mr. Bishin) The question is, isn't it true, Mr. Ogden, what you stated is not true and that the FDA's publications do not state the criteria for a new, for a change in a device that has already been cleared?

A My answer to that would be that the FDA has a guidance document which specifically addresses whether a manufacturer should submit a 510(k) when they are changing their device.

Q That's right. And that document is called, that document is called, quote, Deciding when to submit a 510(k) for a change to an existing device, unquote. Isn't that correct?

A Yes.

Q All right. And in that device, they specifically say, don't they, that the key consideration, the key consideration is whether the change, quote, could [2402] significantly affect the safety or effectiveness of the device, unquote? Isn't that what it says?

A It says that, yes.

Q That's what it says. And in talking about the device, it says that the regulatory criteria statement of premarket notification must be submitted when the device is one that the person currently has in commercial distribution or is reintroduced into commercial distribution and is about to be significantly changed or modified in design, components, methods

of manufacture or intended use, the following constitutes significant changes or modifications that require a premarket notification. One, a change or modification of the device that could significantly affect the safety or effectiveness of, the device; e.g., a significant change or modification in design, material, chemical composition, energy source or manufacturing process. Two, a major change or modification to the intended use of the device.

Isn't that what they say?

A Yes.

Q Okay. Now, you don't know whether this device that Dr. Ames purchased – First, let me strike that for a moment.

The FDA does not require a clearance, does it, of a [2403] device, simply because it changes its name; isn't that correct?

A That's correct, with the caveat that, as long as the name change does not imply a new indication for use or intended use.

Q As long as the labeling doesn't say that; isn't that right?

A Yes.

Q Okay. So that if the manufacturer of their DCM changed the name to listen or used that name as its brand name, that wouldn't require a new clearance for DCM, would it?

A Correct.

Q Now, secondly, if the manufacturer of the DCM decides to offer it with software that did not significantly change the, that did not raise any new issues of safety or effectiveness and which did not have any different labeling from the labeling that was approved by the FDA, that would not require any new clearance either, would it?

A That's correct, as long as there was no need for any clinical data to show substantial equivalence.

Q Okay, that's right. Now, when you deal with people who are seeking either clearances or approvals, do you ever, do you ever suggest to them or have you ever suggested to them changes in the way they make their application?

[2404] A Yes.

Q For example, when you get a premarket notification from a manufacturer and it has, maybe, a number of different uses on it, have you ever said, well, you know, we're not going to be able to clear that with those uses listed on the label, but if you take some of them off, then we might be able to clear it? Have you ever done that?

A Yes.

Q And in some of those situations, have you then cleared the device?

A Yes.

Q Okay, good. Now, have you ever had a situation where someone has come to you for premarket approval and you've told them something like, well, we can't give you a premarket approval right now because you just haven't gotten enough data for us yet, we need more clinical trials than this to do this, or you had some other reason, and so you said to them, but you know what you can do, if you want to get this on the market, you can change your labeling so that you have a labeling which indicates that it has the use of a predicate device, and we can give you a clearance to get it on the market, but you'll have to limit your labeling claims to the ones that are approved in the clearance. Have you ever [2405] done anything like that?

A Yes.

Q And that's something that – You are not the only one who's done that; isn't that correct?

A Correct.

Q I mean, that's part of the service function of the FDA's device division in working with and helping manufacturers who seem like reputable businessmen; isn't that right?

A Yes.

Q Now, are you familiar with the bone screws that have caused so much litigation in this country, bone-screw litigation that was – I can't remember the name of the company. Was it Accupath?

Did you deal with that in your division?

A It was dealt with in my division, yes, but not in my branch. So I'm only peripherally aware of the bone screws, which I believe are called pedicle screws?

Q That's exactly right. Those are the ones I had in mind.

So that was just something you talked about in the FDA maybe at lunch but you actually didn't officially have to deal with?

A Correct.

Q And those bone screws, they are the subject of that fairly recent United States Supreme Court case, [2406] *Buckman v. Plaintiffs' Legal Committee*? Do you remember that?

A I'm not aware of that case.

Q All right. Are you aware of the issue that was involved with regard to the bone screws that, originally, the manufacturer applied for, applied for a clearance for the bone screw as it was to be used as a pedicle screw in the spine, and the FDA turned them down? Do you remember that?

A Not specifically.

MR. ARMSTRONG: Objection, Your Honor, just to this line of questioning, on the relevance.

MR. BISHIN: Well, I'm done with it.

Just a moment. I'm not done with him.

How many minutes do I have, Your Honor?

JUDGE DeBUSSCHERE: Objection sustained, on the issue of bone screws.

MR. BISHIN: How many minutes do I have, Your Honor?

JUDGE DeBUSSCHERE: You have ten more minutes. That will be 2:00.

Q (By Mr. Bishin) I have ten pages of questions for you, Mr. Ogden, but it's not going to happen, obviously. So I have to pick and choose my best questions.

Now, any individual or entity can seek a clearance; [2407] isn't that right, Mr. Ogden?

A Yes.

Q Let's assume that an inventor seeks a clearance and he gets one from the PTA for a particular device. Are you still with me?

A Yes.

Q Okay. And then the inventor decides to assign his device to a company. Are you still with me?

A Yes.

Q Okay. And the company then manufactures the device and distributes it. That company does not

need to seek its own clearance for that device; isn't that right? It can rely on the inventor's clearance?

A That's correct.

Q Now, bear with me, please. The FDA, when it decides whether or not a, when it deals with a notion of intended use, unquote, quote, intended use, unquote, it deals, it tries to make the determination of the intended use of a device that's submitted to it as part of its general evaluation and approval process; isn't that correct?

A Yes.

Q And when it does that, it limits itself, does it not, to the use that is stated on the labeling that is submitted with the application; isn't that correct?

[2408] A I would change that around to say that the device is limited to the labeling for which it is approved, not when it's submitted.

Q The device is limited, the device cannot be marketed or promoted for any other use than the one on its label that's been approved; isn't that correct?

A Yes.

Q You look at labels, and then you approve the label; isn't that correct? When you approve the device, you are approving the label; isn't that correct?

A Yes.

Q If you don't like the label, you are not going to approve the device; isn't that correct?

A Yes.

Q But on the other hand, when the manufacturer submits a device to you and says that this is the use and the only use we're going to put on this label, you can't go beyond that and say, well, we're not going to give you the clearance or approval because we think that people are going to use it for something else; isn't that correct?

A Correct.

Q You are bound, just as the manufacturer is bound by what's on the label, you are bound by what's on the label, too. The statute specifically says that, doesn't [2409] it?

A Yes.

Q Now, Mr. Ogden, you've met with or talked to Mr. Armstrong how many times prior to this testimony that you are giving today?

MR. ARMSTRONG: Objection, Your Honor, relevance.

JUDGE DeBUSSCHERE: Goes to – It's relevant.

Go ahead and answer the question, Mr. Ogden.

A I believe, five or six times.

Q (By Mr. Bishin) You've spoken to him five or six times. Now, I tried to talk to you, didn't I?

A You left a message on my voice mail, yes.

Q Actually – We won't go into that. But I left a message, I say I left you eight messages. But you say you did receive a message of mine, didn't you?

A Yes.

Q And you did not call me back, did you?

A I did not.

Q So you've never spoken to me except when I was deposing you or when I'm examining you right now; isn't that correct?

A Yes.

Q But you have spoken to Mr. Armstrong five or six times

* * * *

[2412] Q And there's also something called an investigational device exemption; isn't that correct?

A Yes.

Q When you get any one of those things, that means you can market a device, isn't that right, or not the latter one, you can't market it, but you can send it in interstate commerce; isn't that correct?

A Right.

Q Now, when the FDA approves a 510(k) premarket notification, that is not, that does not mean that the – Well, let's say when it disapproves. Let's say when it disapproves. That doesn't mean that the device is not safe or effective for the intended use, does it?

A It means that agency has found the device to be not substantially equivalent to a predicate device, and therefore, does not go to market.

Q That's right. It has to be substantially equivalent to a device that's already on the market. It may be safe, it may be effective, but it's not substantially equivalent. And therefore, it's not entitled to a 510(k) clearance; isn't that correct?

A Yes.

Q Now, we get to a premarket approval. Those are the ones that require a lot of data and support; isn't that right?

[2413] A Typically, yes. Safety and efficacy.

Q You have to have, you have to make a strong showing to the FDA ordinarily, don't you, that there's efficacy and safety –

A Yes.

Q – to get one of those.

And sometimes, that can take years and years; isn't that true?

A Yes.

Q And those can be very expensive, can't they?

A That's what I hear. I don't have any personal knowledge of that.

Q They take a lot of the FDA's time, don't they?

A They do.

Q So they are expensive to us, the taxpayers; isn't that correct?

A Yes.

Q So there's business time involved, too.

Now, you turn down a premarket, when you refuse to give a premarket approval, that doesn't mean, does it, that the device is unsafe or ineffective necessarily, does it?

A We would turn it down based on the device having failed to be shown safe and effective for the intended use they were applying for.

[2414] Q Right. In other words, they haven't given you enough evidence yet for you to give them the right to go to market; isn't that right?

A That could be one scenario, yes.

Q Well, let's talk about that one scenario. Now, that can happen, and the manufacturer eventually or some other manufacturer eventually can get a

premarket approval by getting more information to the FDA; isn't that correct?

A That could happen, yes.

Q Or could be some scientific development which would make it kind of clear that the device is effective or is safe or something of that sort, and therefore, merely calling that to the attention, of the FDA might change its mind. That's a possible scenario, too, isn't it?

A Yes.

Q So in other words, the FDA, when it withholds its sanction to go to market, it's doing it in order to be, to be safe, but it doesn't necessarily mean that any device it doesn't permit to go to market isn't a good device or isn't effective. It simply means it hasn't met the criteria the FDA is letting down at this time or at that particular time for getting such an approval or clearance; isn't that correct?

A For that labeling.

Q For that labeling, that's right.

* * * *

[2419] ask about the hypothetical?

MR. BISHIN: Now, I'm forgetting what I wanted to ask about. One of the things I wanted to ask about is the hypothetical.

JUDGE DeBUSSCHERE: Go ahead.

RECROSS-EXAMINATION

BY MR. BISHIN:

Q First of all, what you said was that if the manufacturer was, even though they had a clearance that covered one use, they were only selling it for another use to, I don't know who, the same customers, that your understanding was that the compliance division would take, would want you, would want them to come in and seek another clearance. That's what you testified to, isn't it?

A Yes.

Q You don't know if the manufacturer of the device that Dr. Ames purchased was selling it to people for only one use, do you?

A I do not.

Q You don't know what claims the manufacturer of that device was making at the time that he sold that device to Dr. Ames, do you?

A Correct.

[2420] Q You don't know what that label looked like at that time; isn't that correct?

A Yes.

Q You don't know how Dr. Ames was using the device; isn't that correct?

A Correct.

Q Now, Mr. DeMarco told you not to speak to me. He didn't tell you not to speak to Mr. Armstrong; isn't that correct?

A Yes.

MR. BISHIN: I'll stop there, Your Honor.

JUDGE DeBUSSCHERE: Opportunity for panel members to ask questions.

Mr. Tennis, do you have any questions?

MR. TENNIS: Yes.

EXAMINATION BY THE PANEL

BY MR. TENNIS:

Q Hello, Mr. Ogden. First of all, a simple question. Everybody has been talking about labels. Is that something that's on a sticky thing you put on a device, or is that a term that's used in some of the literature that goes with the device?

A We use the term "labeling" in a broad sense. It means any written or voice information that accompanies the

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[2935] **STATE OF WASHINGTON**
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent.	)	**No. 02-06-A-1012MD** Day 4 – PM

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

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[2957] JUDGE DeBUSSCHERE: We're back on the record. Mr. Clark was testifying, I think they were finishing up questions. Mr. Bishin, do you wish to call Mr. Clark or have Dr. Ames testify?

MR. BISHIN: I think we have to let Dr. Martin testify.

JUDGE DeBUSSCHERE: Okay, Dr. Martin, and we'll have to excuse Mr. Clark, because otherwise I don't know how much time it will take for Mr. Clark, because we've scheduled Dr. Martin for one o'clock, so I think that's what we have to do. So we'll have to call you in your room I guess. Are we all ready to go?

JUDGE DeBUSSCHERE: Yes. Your next witness, Mr. Bishin.

MR. BISHIN: Dr. David Martin, have a seat right there, Dr. Martin.

JUDGE DeBUSSCHERE: Would the court reporter swear this witness in.

* * * *

DR. DAVID MARTIN,

having been first duly sworn by the Notary, testified as follows:

JUDGE DeBUSSCHERE: Can you tell us your full name.

THE WITNESS: David Reed Martin.

JUDGE DeBUSSCHERE: And it's M-a-r-t-i-n?

[2938] THE WITNESS: That's correct.

JUDGE DeBUSSCHERE: Your witness, Mr. Bishin.

EXAMINATION

BY MR. BISHIN:

Q Dr. Martin, it would not be impolite for you to not look at me and talk to me when I'm asking you questions, but instead talk to the panel and the presiding officer because they're the ones who have to really hear. So as unnatural as that may seem, would you try your best to talk in that direction; thank you.

Would you state your occupation, please?

A I'm a family physician and an acupuncturist.

Q An acupuncturist. And can you describe kind of generally the kind of practice you have, a little bit more elaborately so we understand kind of the details of it?

A I currently have a private practice in Seattle focused on, primarily on constitutional acupuncture; there's a lineage of acupuncture called thigh element acupuncture and I see usually eight to 10 people a day for anywhere from 45 minutes to two hours each, working with the energetic constitution of the individuals.

People come for basically the whole variety of Western medically trained reasons, although usually not for very acute causes that would more likely take them into an [2939] emergency room.

Q Okay. Do you find yourself involved with patients who have allergies?

A I certainly do.

Q Do you ever treat patients for allergies?

A I do.

Q Are you familiar with the general conventional medicine with respect to allergies?

A I'm familiar, yes.

Q And does conventional medicine, conventional approach to allergies, does it differ in significant respects from the approach that you have with respect to allergies?

A Yes. The entire framework that is used to treat allergies in acupuncture is different from Western medicine.

Q I'm going to go into that in a moment, but I just wanted to have a topic heading for this examination. Would you please give us your entire educational experience; where you went to school after secondary school and what degrees you received, what formal training you had; would you tell us that?

A Yes. I went to college at Dartmouth College and majored in math, physics, and engineering; did a year of graduate study at the Thayer School of Engineering at Dartmouth College, primarily focusing on computer [2940] architecture and theoretical physics prior to going to the medical school program at Harvard University, joint program between Harvard and M.I.T. for people with strong quantitative science backgrounds; graduated from the medical program at

Harvard Medical School in 1983 and attended three years of family medicine residency at University of Oregon Health Sciences Center; and then did two years of the Robert Wood Johnson Fellowship in the faculty at the University of Washington, Seattle.

Subsequently in 1994, '95, and '96, I trained in acupuncture at the Wu Hsing Toe School in an apprenticeship role in Seattle, graduated from there and took the national boards in acupuncture just in 2001. Mainly because some people who look at medical doctors practicing acupuncture from the acupuncture field don't necessarily think they have any credentials.

Q So your M.D. is from Harvard then?

A That's correct.

Q And do you have any informal training of any kind that supplements your formal education; any other kinds of courses that you've taken in specific fields of any kind?

A I've taken, you know, I do what would be the equivalent of continuing education, usually at least a week or two a year in observing senior acupuncturists in a particular lineage of acupuncture; and I've over recent

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[2960] Q And when you treat them how do you do it?

A In the same manner that I described in the example. I look at their constitution and I treat them based on their constitution; and if there are specific areas they are having allergies in, such as allergic rhinitis, they may get specific symptom-oriented points done for those. But in the way that I'm treating them to cure their allergies, is the way that I described.

Q In the field, in the broad field of acupuncture, do acupuncturists, do the, does a respectable opinion in acupuncture areas believe that allergies are something acupuncturists are competent to treat?

A I'm not aware of allergies being treated, being studied in any large studies as a group. Allergic rhinitis, for example, is one area that has been studied and is, you know, recognized by the World Health Organization as being one of the areas that acupuncture is involved in treating in individuals. Asthma, not really specifically allergy-related asthma, but asthma as a whole is also recognized as another area that acupuncture is useful in treating.

You know, as with Western medicine, there are many areas that acupuncture is used for that there have not yet been randomized control double-blind studies done for and there's some reason to believe that such studies don't [2961] necessarily have the same applicability in a medicine based on energetics. The same utility I would say, in medicine based on energetics as they do in Western medicine because of

the effects of the consciousness of the practitioners and the outcome of the studies.

Q I'd like to go into that a second, but that wasn't my question. My question was, not does Western science accept acupuncture for allergies, but does acupuncture accept acupuncture for allergies?

A Acupuncture accepts acupuncture for allergies. Now again, according to the different lineages there are different, some lineages have very little to do with allergies and other lineages have a lot to do with allergies and will treat them and will successfully.

I can think of many, many examples of acupuncture that is useful for treating allergies; so from my perspective, yes.

Q I'd like to get back to something –

MS. PAXTON: Mr. Bishin, can I just ask one question about a definition; lineages. How are you using that term?

A Just that the way acupuncture has been passed down over the years was really for thousands of years in small groups, in families and there are kind of different perspectives and different aspects that are developed in

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[2963] not deal with these same levels of existence as Asian medicine on which acupuncture is based, on

which acupuncture represents; is that what you're saying?

A Well, in my understanding Western medicine, most of Western medicine is biomedicine, it's based on material reality; there are aspects of medicine, psychology, psychiatry, which bring in other levels, you know.

There are kind of psychosocial levels brought in, but that still occurs within a framework where it's almost understood implicitly that the mind, if you will, is generated by the brain and it all has a material basis and that's not the point of view from the East where consciousness is actually more fundamental than the material level of reality.

Q Could you elaborate a little bit more on what sense is consciousness more fundamental than the material level?

A When I say it's more fundamental, I mean that in the particular world view that acupuncture is based on and I'll give a more concrete example of this, but that treating things on the energy level can heal things on the physical level.

And so the physical level in some sense is dependent on, or doesn't determine the energy level the way the energy level can determine the physical level, and in my early experience in acupuncture I was shocked at times

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[2968] used where a glass container is placed on the skin and it's burned inside it to create a vacuum; bleeding can be used, a variety of different –

Q And is acupressure related to acupuncture?

A Yes. It uses the same points, basically stimulates the points with a non-invasive means rather than a needle.

Q And you say non-invasive means, what kinds of means are we talking about?

A Just pressure and often an amount of motion or pressure on the point.

Q Is it possible to do acupressure with something like what's in front of you; do you recognize that?

A Certainly.

MR. ARMSTRONG: Objection, vague.

JUDGE DeBUSSCHERE: The question's vague; could you please have the witness –

Q (By Mr. Bishin) Would you please describe what's in front of you, the device?

A It's not something that I'm familiar with as a specific device, although it appears to me that it's along the line of devices that provide a mechanical level of stimulation to these points which are then placed on points on the body to give mechanical stimulation to those points.

Q Would you just briefly describe for the record, what it is you're holding in your hand?

* * * *

[2970] system.

A Yes. You know, I will often use some acupressure in my treatment if the point doesn't need the amount of stimulation that acupuncture will give it; acupressure is useful. I often use acupressure with children who don't need very much stimulation. So the same fundamental view is underlying acupressure as well as acupuncture.

Q Now, in the acupuncture community, is acupressure ever used to treat allergies?

A Yes.

Q Are you familiar with any schools or methods that do treat allergies with acupressure?

A Several different schools, there's NAET, Nembudripad Allergy Elimination Technique; there's TAT, Tapas Acupressure Technique; there are others, Allergy Relief System, ARS is another technique.

Q These all use acupressure for this purpose?

A Right.

Q And are these regarded as respectable among the acupressure/acupuncture community?

MR. ARMSTRONG: Objection; respectable.

MR. BISHIN: I'll say there is a doctrine of law, Your Honor, that says respectable minority, I don't want to get into the majority because there aren't any, you judge by the standards of that respectable minority, that's [2971] why I'm asking with respect to minorities.

JUDGE DeBUSSCHERE: Overruled.

MR. BISHIN: Would you read back the last question, please?

THE REPORTER: (Complying)

A There are certainly groups, again there are many lineages of acupuncturists and some acupuncturists would use modalities like this. And there are many people practicing these particular modes of allergy treatment within the acupuncture community as a whole.

And from my particular personal perspective, I've certainly seen clients of mine get treated with these methods and get relief from their allergies, sometimes in ways that I am clear that it came from the treatment.

For example, I had one, about 33-year-old woman, who had had G.I. distress and skin allergies for years and had been through Western medical treatment for years; had been on elimination diets fairly strict, keeping off all wheat, all dairy, a variety of other things I can't recall at the moment; and she went into NAET treatment and over the course of a

year all of her allergies completely resolved. She now eats whatever she wants to and has no problems.

Q (By Mr. Bishin) The types of people that practice NAET, do they have the standard kinds of certification and [2972] credentials that are considered to be respectable or desirable in the acupuncture community?

A Because NAET is an acupressure technique it doesn't necessarily require the licensing that is required of acupuncturists. It does require that people be, as I understand it, and I'm not an expert on this, but as I understand it NAET training is open to people who are licensed in one way or another to treat people for illnesses. And there is a set of courses that people go through at NAET and I think there's an ongoing education requirement to be considered a practicer of NAET or registered practitioner, that kind of thing.

So there is a training protocol for it and the acupuncturists who practice it are certified as acupuncturists by means of the way that they got there in the first place.

Q So the types of people that practice it, though, are there among those people, people who have credentials that are generally recognized by the, even by the medical community but certainly by the acupuncture community?

A Yes.

Q For example, do physicians practice NAET?

A I imagine that they do; you know, you're asking me a little bit more than I'm familiar with about the NAET practitioner group. Most of the people that I know that [2973] practice NAET are acupuncturists, but I know that chiropractors practice it and I know that doctors can practice it. I just, to this point in my acquaintance with people, haven't found specific doctors that practice it.

Q Now, how would you compare the success of acupuncture and acupressure in treating allergies with the success of Western medicine?

A Could you ask me a more specific question?

Q I was hoping you would break it down. First of all, let me, are there significant number in your opinion of instances and situations in which acupuncture or acupressure is able to get positive results for people who are suffering from allergies when Western medicine is unable to deliver such results?

A Yes.

Q Can you tell us a little bit about that, more general things?

A Well, you know, the options within Western medicine for treating allergies are few. There are a number of methods for symptomatically reducing the effects of allergies.

There are for some types of allergies, such as allergic rhinitis and allergy-related asthma, there are immunotherapy protocols that can be used in

Western medicine, but immunotherapy protocols are not particularly [2974] helpful for food-related allergies or food-intolerance as far as we know.

And so there are often not a lot of ways to cure allergies from the Western medical perspective. And even when using immunotherapy there are risks, there are, you know, dozens of people have died over the last few decades due to scratch tests and due to immunotherapy applications in Western medicine.

From the acupuncture perspective, you know, what's bothering the person that is looked at as an allergy from the Western perspective is seen as a pattern that isn't necessarily labeled as an allergy, and often the individual can be brought into an equilibrium where that is not, doesn't bother them nearly as much from the acupuncture perspective, and with very little side effects, a little bit, of an ouch with a needle.

Q So the side effects, are there any situations in which death has occurred because of the acupuncture or acupressure treatment of allergies?

A None that I'm aware of. They are very rare in acupuncture as a whole if a needle that is too long is stuck in the wrong place, in the lung for example, it can cause a pneumothorax which can be, can lead to death if appropriate help and recognition of the syndrome is not, but that's very, very, very rare. I've never heard of it

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[2976] there are RASP tests that look at the antibodies in the blood stream.

But, you know, getting a skin test and even more so with the RASP test, the standard directive in a medical textbook would be that you can't trust them whether they're positive or whether they're negative. A RASP test is at best confirmatory to some degree if you're considering there's an allergy in some area. There are many, many false positives, there are false negatives, they just cannot be counted on as a diagnostic method, and so they're available and they're part of the Western medical system, but they're not very accurate.

Q Let me ask you, are you familiar with kinesiology or muscle testing?

A Only secondarily, it's not part of my practice, I've never studied it.

Q But in the course of, is it something that's done by acupuncturists as part of –

A It's not really part of acupuncture as a whole, but it's a part of alternative medicine. I'm familiar with it in my wider familiarity with people who practice alternative medicine. I know chiropractors who use it, some naturopaths who use it, you know, it's integrated often into methods like NAET that are used by acupuncturists, but it's not a specific part of [2977] acupuncture.

Q In the alternative world is it something that is considered to be a respectable device by a significant number of people?

MR. ARMSTRONG: Objection; if I understand counsel, he's saying kinesiology is a device.

JUDGE DeBUSSCHERE: Objection sustained; can you clarify your question?

Q (By Mr. Bishin) I won't characterize it as a device or a process or anything. Is muscle testing or kinesiology considered to be among a significant number of people in alternative medicine a useful phenomenon?

A Well, I would say two things; one is based on the fact that a considerable number of people in alternative medicine use it, that it must be considered useful.

It, in my experience, is useful in the hands of some individuals and I've seen people who seem to be very effective in the treatment they give based on kinesiology, but I can't give you any literature kind of overview or assessment of the field as a whole other than it is definitely respected by people when it's in the hands of certain people.

Q Now, you were talking a little bit near the beginning of this examination about whether or not the most typical

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[2985] there are a possibility of things like that.

It also mentions that there are times in the process of treatment with acupuncture when the symptoms the individual is having may flare up and be worse than they were previously.

Q One last question. You mentioned the term EDS, electrodermal screening?

A Yes.

Q Are you aware of –

A I think I mentioned electrodermal device.

Q Device?

A Yes.

Q Do you know if electrodermal device can diagnose an allergy in the skin?

A I don't know the answer to that. I actually did some research on that for this particular occasion and the last time that the Clinics of North America put together a panel statement, entire issue evaluating allergy diagnosis and treatment, which was in 1995, they said that electrodermal screening was as yet untested.

And when I did a Medline search I found nine or 10 papers that came up with the words electrodermal allergies over the last nine years, and there are some of those that report that in double-blinded trials they are successful in diagnosing allergies, and there were

some of [2986] them that said there is no effect; and this goes back to this example about the issues of the mind and the problem with doing the research that we were talking about.

And like in many areas early studies don't all tend to go the same direction; so, you know, I think my assessment would be in some peoples' hands these work.

Q Okay. The second part of my question is, would electrodermal screening, would that cure an allergy based on your experience and knowledge?

A Well, my understanding of the term electrodermal screening isn't a diagnostic treatment.

Q Okay, so it's not a treatment; it's a diagnostic tool?

A Well, electrodermal screening particularly is screening for something and if it's electrodermal allergy screening you're talking about screening for allergies.

MR. ARMSTRONG: That's all; thank you, Doctor.

JUDGE DeBUSSCHERE: Questions from the panel members; Mr. Tennis?

EXAMINATION

BY MR. TENNIS:

Q You said at some point that, so we're dealing with the difficulty of the two worlds you live in, the Harvard M.D. world and the acupuncture world, that you changed the sign on your office; did I hear you correctly?

[2987] A Oh, what I was referring to is in my medical practice, at that time at Group Health there was a little sign up saying that I'm not in the office on Mondays because I'm starting up an acupuncture practice; so a lot of people wanted to come because of that and I took that sign out of there because it just wasn't the best way to start working with people.

Q Okay, I thought you had an acupuncturist in sign or something like that.

A No, they were separate offices.

Q And you were in Group Health but now you're in private practice?

A That's, right.

Q Colleagues or just by yourself?

A In the physical location that I'm at, there's a naturopath and a Ph.D. counselor and I have people coming through for training, that kind of thing, so there are colleagues there but I'm the only five-element acupuncturist full-time.

Q Do you use any devices in your treatments or practice?

A I don't.

MR. TENNIS: That's all I have.

JUDGE DeBUSSCHERE: Dr. Uberoi?

A (Continuing) I mean other than needles and moxa; the needles got off the experimental device a few years ago for [2988] acupuncture, the FDA kept them as an experimental device for I don't know, 10 years or so.

JUDGE DeBUSSCHERE: Dr. Uberoi, do you have any questions?

DR. UBEROI: Just give me a few seconds.

JUDGE DeBUSSCHERE: I'll ask Ms. Paxton and then you can come back.

EXAMINATION

BY MS. PAXTON:

Q Dr. Martin, I'm not sure because of your previous response about kinesiology if you're able to answer this question, but I'm going to shoot it towards you and see what you can do with it. We've been told that there's muscle testing involved with allergy testing in this case to find out what actual food in this case rather than a pollen or grass or whatever is the culprit in somebody's allergy?

A Right.

Q And that there is a way of delivering that message to the person, to the patient in conjunction with pressing down on an arm and resistance. Are you with me so far?

A Yes.

Q In this case we have been dealing with this machine which is to your left, which without going through all the what is it and who is it and all that, that its to your

* * * *

[2993] **EXAMINATION**

BY DR. UBEROI:

Q One is that would you treat somebody with DR-5 element acupuncture schooling just based on a RASP test, RASP test on like egg allergy six, the person says I don't like eggs but I keep eating them and I don't have any symptoms; I understand you might want to treat the patient anyway for other things and balance.

A I, generally when I talk with people on the phone about whatever they're coming in for, even if it's something I know is very amenable to acupuncture, I ask them generally speaking if this is just a bother and they just want the symptom to go away or whether they're really looking at this as having something to do with their overall balance and

lifestyle and they're really willing to work on another level about what is this symptom, why is it coming.

From my understanding, a RASP test showing an egg allergy with no symptoms needs no treatment by anybody. And the only reason that I would treat someone like that is if they really were in a place of wanting to get constitutional acupuncture for its preventative benefits rather than treating them.

Q Right, okay; one more question. When you said treatment you mean – I wouldn't want to use the word energy

* * * *

[2519] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD Day 3

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

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Renton, Washington
January 15, 2004

REPORTED BY JEAN ERICKSEN, CCR

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[2692] afternoon break. It's now 3:55 p.m., and the Respondent is presenting his case in chief.

Let's go off the record while I dial the number.

(Off the record.)

JUDGE DeBUSSCHERE: This is Health Law Judge Arthur E. DeBusschere, and this is a matter before the Medical Quality Assurance Commission. Mr. Bishin has identified you as a witness, okay?

PATIENT 2: Yes.

JUDGE DeBUSSCHERE: All right. Let me briefly give you more introduction so you understand who's calling you.

My name is Arthur E. DeBusschere. I'm the presiding officer, health law judge presiding over this hearing. This hearing is being conducted at the Renton Holiday Inn select hotel in one of the conference rooms.

This conference room, the hearing is being recorded by a court reporter, so testimony that you will be giving will be recorded by a court reporter. There are commission, Medical Quality Assurance Commission members here, three commission members,

Mr. Tennis, Doctor Uberoi and Ms. Paxton are commission members that are hearing this.

[2693] The Assistant Attorney General, Mr. Keith Armstrong, is here representing the Department of Health, and Mr. Bishin is here with Doctor Ames, representing, Mr. Bishin is an attorney representing Doctor Ames, who is also present.

This is a public hearing, so there are two or three other individuals in the room.

Patient 2, I'll ask the court reporter to swear you in.

Can you hear me okay? I should have asked you that first. Can you hear me okay?

PATIENT 2: Yes, I can.

JUDGE DeBUSSCHERE: If you can speak up the most you can, I would appreciate it.

PATIENT 2: Okay.

JUDGE DeBUSSCHERE: Will the court reporter swear this witness in.

* * * *

PATIENT 2: Having been first duly sworn, testified as follows:

JUDGE DeBUSSCHERE: Could you tell us your full name.

THE WITNESS: Patient 2.

[2694] JUDGE DeBUSSCHERE: And your last name is spelled Patient 2?

THE WITNESS: Right.

JUDGE DeBUSSCHERE: Patient 2, your testimony is being transcribed by a court reporter. What I will ask the court reporter to do, because of the Health Care Information Act, and you have been identified as a patient, is that Mr. Bishin and Mr. Armstrong and maybe the panel members who might ask you questions, can refer to you as Patient 2, but the court reporter will transcribe your name as Patient Number 2.

THE WITNESS: Okay.

JUDGE DeBUSSCHERE: So the record will reflect Patient Number 2 testifying, but you'll be identified as Patient 2 and testify as Patient 2.

Mr. Bishin, your witness.

* * * *

DIRECT EXAMINATION

BY MR. BISHIN:

Q. Good afternoon, Patient 2.

A. Good afternoon.

Q. Can you hear me?

A. Yes, I can.

Q. Patient 2, can you tell us where you live?

[2695] A. I'm sorry, I can't hear you as well as I thought I could.

Q. I'm going to move a little bit closer, so I'm more in line with the speaker phone. Can you hear me better?

A. Yes, I can.

Q. Patient 2, where is your place of residence?

A. Richland, Washington, address 2612 Saddle Way.

Q. And what is your employment?

A. I am employed by Duratek Hanford Company as quality assurance manager of the project Hanford Management Contract on behalf of Fluor Hanford.

Q. What does that position entail?

A. The position entails managing the overall quality assurance program for this prime contract at the nuclear facility, as well as performing, managing the performing arts, assessments of ongoing work activities.

Q. Can you tell us a little bit more about what quality you are assuring?

A. We are assuring quality in accordance with MGM 830 Subpart A, which are the Nuclear Safety Quality Assurance Requirements, a federal regulation.

Q. Okay, and how long have you been doing this [2696] job?

A. This current job approximately five years, but I have 20 years experience at Hanford, 32 years overall in quality assurance.

Q. Thank you. Approximately how many employees of your company report to you?

A. Nine.

Q. Now, are you familiar with Doctor Geoffrey Ames?

A. Yes, I am.

Q. Can you tell us how it came about that you became familiar with him?

A. It was actually my wife that was looking for a new doctor, and Doctor Ames was just opening his practice in Richland there. She called and made an appointment. She liked him, and most importantly, she liked the fact she had finally found a doctor that was willing to LISTEN to her, and he became our family physician.

Q. Okay. Now, in the course of your relationship with Doctor Ames, have you ever consulted him with respect to any allergies of any kind?

A. Yes, I have. I had a couple of significant allergies one of which was to tomatoes, and the [2697] reaction I was having to tomatoes was that it would cut off my windpipe and would cause me to go

through a series of rather severe throat clearing exercises until I could breathe again.

The other allergy was an allergy that turned out to be to sugar. I had no idea what that one was until I went to Doctor Ames, but I was getting very severe headaches that I noticed after eating certain foods.

Q. Okay, and did Doctor Ames treat you for the allergy that was connected to tomatoes?

A. Yes.

Q. All right, and do you know what the result was?

A. The result was very positive. After the treatment I have been able to eat tomatoes ever since.

Q. And you have never had any symptoms?

A. No side effects.

Q. I burden of proof? [sic]

A. I said I have been able to eat tomatoes ever since the treatment, with no side effects.

Q. So the symptoms that you described before, disappeared entirely?

A. I'm sorry.

[2698] Q. I said are you saying that the symptoms that you just described about your throat disappeared entirely?

A. Yes, that's true.

Q. Now, with respect to the sugar, were you treated for that?

A. Yes, I was.

Q. All right, and let me ask you this: what was the treatment that was employed for the tomatoes?

A. The treatment involved Doctor Ames using the machine, and I'm sorry, I don't recall the name of the machine, but it involved me holding a probe in one hand, and Doctor Ames would give me a strength test which consisted of me lying on my back with my left Armstrong up in the air, and he would apply pressure to my arm.

If it was a negative reaction, I was able to resist the pressure very easily, however if it was a positive reaction, I was unable to resist, and my arm would fall.

Q. Did he then treat you after that?

A. Yes, he did.

Q. What was the nature of the treatment?

A. Again, I don't remember the name of the apparatus, but it involved a technique of him using [2699] the machine going up and down my spine, and then he would massage certain areas on my hands and feet.

Q. And I'll come back to the device for a moment a little bit later on. With regard to the sugar allergy, did he treat you for that, also?

A. Yes, he did, and that was most interesting because we didn't have any idea what could be causing it, so he actually tried multiple causes, and all kinds of different foods, and I was able to resist the strength portion of the examination on everything except sugar. When we finally tested for sugar, my Armstrong collapsed. It was just incredible.

Q. All right, I was going to wait to talk about the machine, but since you have said it again, when your arm collapsed, did you make an effort to resist?

A. Absolutely. Absolutely. It had become sort of a challenge, you know, because he asked you to give him strength, so you really tense your arm up, and there is quite a bit of strength exerted in that, and that's what makes it more amazing, when you do find the thing that you're allergic to, your resistance is almost completely gone.

Q. Let me ask you this: Did he do this procedure on your back once he –

[2700] A. Yes.

Q. I burden of proof [sic], in connection with the hypothesis that you had a sugar allergy?

A. Yes.

Q. He did, all right. Did you have any evidence that it had any effect?

A. Yes, he tested me again, as he did before, and I was able to resist it completely.

Q. What happened to your symptoms, though, was there any affect on your symptoms?

A. The symptoms have disappeared. I'm now able to eat sugar, which might be unfortunate, but, yeah, I can eat sugar just fine now.

Q. Okay, and let me just make sure for the record to clarify this. With respect to the tomato allergy, when he tested you, did he test you with that same muscle testing procedure, with testing your muscle and having you hold the probe, and then testing your muscle again?

A. Yes.

Q. And you became weak when he typed in tomato; is that what you're saying?

A. That's correct.

MR. BISHIN: That's all I have, Your Honor.

* * * *

[2707] A. I do not.

Q. Patient 2, have you ever been diagnosed with sugar allergy or tomato allergy before Doctor Ames?

A. No, sir.

Q. Have you had any treatment by another health care provider, after Doctor Ames treated you for sugar and tomato?

A. Not for allergies.

Q. Have you ever had allergies come up on any other test by another profession?

A. No.

Q. You mentioned – let me ask you a question about, you mentioned that there were multiple exams for the sugar?

A. I'm sorry, I missed that. Would you repeat it, please?

Q. You mentioned that you had multiple exams to determine that it was a sugar allergy that you had; is that correct?

A. Yes. Yes, he tried a whole variety of different kinds of foods on me before we arrived at sugar.

Q. So he would type in a different food, and then do the testing, and he would go to another food and then do the testing, is that the procedure?

[2708] A. Yes, exactly.

Q. Thank you, that's all I have.

JUDGE DeBUSSCHERE: Redirect on the questions asked.

Mr. Bishin, do you have any additional questions?

MR. BISHIN: Yes.

REDIRECT EXAMINATION

BY MR. BISHIN:

Q. I have a couple of questions, Patient 2. I just want to make sure for the record, because I'm not sure what the answer turned out to be.

As I understand your testimony the testing involved muscle testing and holding this probe in your hand, and Doctor Ames typing something into a computer; is that right?

A. Yes.

Q. And the treatment involved this procedure on your back?

A. Yes.

Q. Okay, and when Doctor Ames, when you came to Doctor Ames with the food allergy, did he take a history from you, did he ask you about your symptoms, and anything else?

A. Absolutely.

[2709] MR. ARMSTRONG: What was that answer? I didn't hear you.

JUDGE DeBUSSCHERE: Absolutely.

Q. How long after you started seeing Doctor Ames did you come to him for the tomato allergy?

A. Gosh. You're asking an old man a memory question here. I have been going to Doctor Ames for approximately 10 years, my wife and I. My tomato

allergy probably showed itself somewhere around five or six years ago.

Q. Okay. So had Doctor Ames taken histories of you before you came to him with the tomato allergy?

A. Yes.

Q. Do you know if he had a substantial chart for you prior to the tomato allergy?

A. My file there is pretty thick, yes.

Q. Okay, I think that's all I have. Thank you very much. We now have to hear from the Panel.

JUDGE DeBUSSCHERE: Patient 2, this is Health Law JUDGE DeBUSSCHERE Art DeBusschere. The Panel members may want to ask you some questions. I'll ask each of them individually if they do.

Mr. Tennis, do you have any question of Patient 2?

MR. TENNIS: No, thank you.

* * * *

[2714] tomatoes were cooked tomato or a raw tomato, that you would have that reaction of swelling or shortness of breath?

A. No. I would have the same reaction. It was a closing of my throat, sort of gagging and throat clearing rather violently, more violently than I liked it.

Q. Okay, and how soon after you had your treatment for the sugar allergy, did you try sugar?

A. I wasn't as anxious after that one, because the headaches really hurt, so I would try little portions, and then you know there is so many foods that contain sugar, it's almost impossible to avoid them unless you stay away altogether.

I was picking up normal sugars in regular foods, and stuff like that, and it was probably within 24 hours that I decided to try a bite of a cookie, something I knew had a lot of sugar in it, and I had no reaction.

Q. Is there anything else, besides your sugar allergy and tomato allergy, that you have an allergy to?

A. I'm not aware of any allergies right now.

Q. Thank you very, much.

JUDGE DeBUSSCHERE: Patient 2, there may

* * * *

[2805] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD DAY 4 – A.M.

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

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Public Member

Renton, Washington
January 13, 2004

REPORTED BY JEAN ERICKSEN, CCR

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* * * *

[2838] Go ahead, Mr. Bishin.

JUDGE DeBUSSCHERE: We have to swear the witness in, and would you tell us your full name, please?

THE WITNESS: James Hoyt Clark.

JUDGE DeBUSSCHERE: Would you swear in the witness.

* * * *

JAMES H. CLARK,

having been first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. BISHIN:

Q. Mr. Clark, where do you live?

A. I live in Linden, Utah.

JUDGE DeBUSSCHERE: Excuse me. Can you speak up, and face a little more this direction so I can hear you. I'm a little bit of hard of hearing.

A. I live in Linden, Utah.

Q. You don't have to talk to me, even though I'm asking the questions. Talk to the Panel. They're the ones that have to hear you. If I don't hear you, I won't be bashful.

A. Okay.

Q. You live in Linden, Utah did you say?

[2839] A. Yes.

Q. What is your occupation?

A. I am a bioengineer that does development work and software programming.

Q. A bioengineer that does what?

A. Software development.

Q. Do you have a company?

A. Yes, I do.

Q. What is the name of the company?

A. I have a company Health Dimensions International. It's an R & D company.

Then I have Star Tech Health Service. That's a distribution company.

Q. What's an R & D company?

A. Research and development.

Q. What does that company do?

A. That company does software programming for systems and computers in the alternative health field.

Q. And Star Tech Health, what is the nature of its business?

A. Star Tech Health is a manufacturer and distributor in training and service of alternative health instruments.

Q. What kinds of devices does it have on the [2840] market at the present time?

A. Primarily Computerized Electrodermal Screening Devices.

Q. What is a computerized Electrodermal Screening Device?

A. It's a device that is used in alternative health care to take galvanic skin response measurements.

Q. Okay. Now, galvanic skin response, can you tell us briefly what that is; is that pretty much what Doctor Sherman testified to the other day?

A. Yes, it was.

Q. Can you briefly remind us what a galvanic skin response device is?

A. The galvanic skin response device is an ohmmeter. It is calibrated to the specifics of what you're measuring, in this case the skin. It puts a very small current through the body and then measures the resistance of the electrons as they flow through.

Q. Now, the device that your company makes, can you tell us, Doctor, are there more than one model?

A. Yes. There are a number of models, the Orion, the Pegasus and the Mira.

Q. Those are the names of the three models?

A. Yes.

* * * *

[2845] A. They're device listings, the device listings that we submitted to the FDA.

Q. And those device listings are for what?

A. The Orion, Pegasus, Mira.

Q. Now, do these devices indicate that they are relying on the Digital Conductance Meter Clearance?

A. Yes, they do.

Q. Where do they do that?

A. In the proprietary name, line, Box 9 on the device listing form.

Q. Okay. Now what does the, what was the response of the FDA to your sending in this device listing indicating these devices were all digital conductance meters under the classification under HCC?

A. The FDA responded that they already had the listings, and did not need this information.

Q. Okay. Now, Mr. Clark, I'd like to go into your background a little bit, if we may. Can you tell us what your education is after secondary school, please.

A. Okay. I attended Trinity University in San Antonio, Texas, and for a year was in physics. I then transferred to Texas A & M University, and graduated in 1973 in bioengineering. I conducted [2846] research while I was there also. Then I went to the University of Texas Medical Branch in Galveston, Texas.

There I attended studies in medical biochemistry. I found while I was there that I didn't like test tubes, I liked devices, and I went and worked in Houston at the medical center there at the speech and hearing institute, developing information for autistic children while there.

I then returned to Texas A & M, and took a few classes there. Soon after that, after finishing those

classes, I went to Utah and I was able to attend Brigham Young University.

While I was there I got training as an emergency medical technician.

I received a Master's Degree in exercise physiology and a minor in digital electronics. I graduated with a Master's Degree in 1978.

Q. Okay. Is that the extent of your formal education?

A. I also returned to Texas A & M and took physiology from the vet school while studying hyperbaric medicine.

Q. So that would be the extent of your formal education, is that correct?

[2847] A. Yes.

Q. What about your informal education?

A. I have attended a number of classes where I learned about microprocessors and how to use them.

Q. When did you first become involved with galvanic skin response devices?

A. In 1978.

Q. Can you tell us a little bit about how that happened?

A. After graduating with a Master's Degree I was involved with some colleagues in developing courses for microprocessor training.

Microprocessors were a new concept at the time, and one of the people that I was working with met some businessmen that were bringing in Dermatron, a German electrodermal skin device, importing them into the United States, and they wanted to have the device computerized.

The German manufacturer was not interested in computerizing it. They had been making their dermatone for 20 years and selling them around the world, and the idea of computerizing was not interesting for them.

I was asked, because of my background, if I could computerize the device, and that's when I [2848] started on the development.

Q. What was that year again?

A. In 1978.

Q. Since that time how much of your professional or business time has been spent dealing with galvanic skin response devices?

A. Almost the entire time, 26 years.

Q. So for 26 years you have been in this particular area; is that right?

A. Yes.

Q. During that time did you become familiar with the industry, is there an industry of galvanic skin response devices?

A. Yes.

Q. Did you become familiar with the computerized types of galvanic skin response devices?

A. Yes. I'm considered the father of Computerized Electrodermal Screening.

Q. Why is that?

A. Because I was the first one to computerize it, some people out there that have done major publications in alternative health, gave me that title.

Q. Did you start developing your own computerized galvanic skin response devices?

[2849] A. Yes, I did.

Q. Let me ask you, you testified that the – let me ask you this first: Have you been qualified as an expert on computerized galvanic skin response devices?

A. Yes.

Q. By whom?

A. I was an expert witness for a trial in South Dakota before the state court there, and I also was a witness for an educational board in, chiropractic board in Minnesota.

Q. Have you had occasion to observe what goes on in the market for GSR devices, if I may call them that?

A. Yes, I have, worldwide.

Q. Have you traveled outside the United States on business related to galvanic skin response devices?

A. Yes, I have.

Q. How often have you done that?

A. A couple of times a year.

Q. Let me ask you this. About how many manufacturers are there of galvanic skin response devices that engage in the kinds of alternative, that design their products for alternative health care [2850] uses in the United States, would you say?

A. They are probably about 20 to 30 major manufacturers.

Q. And they all manufacture and distribute this kind of device in the United States?

A. I would say this kind of, yes.

Q. And how about outside the United States, any idea how many manufacturers there are of these devices?

A. There are a number of German and Russian and French manufacturers.

Q. And let me ask you this: These devices, are there any states in the United States where these devices are not used?

A. No. They are used throughout the United States.

Q. Are there any states that specifically accept Electrodermal Screening as a modality for a health care practitioner?

MR. ARMSTRONG: Objection.

JUDGE DeBUSSCHERE: Basis?

MR. ARMSTRONG: He has asked the witness are there any states that accept EDS as a modality. That's not relevant to this case. It's not relevant to the whole, it's not relevant, period.

[2851] JUDGE DeBUSSCHERE: It's relevant to the issue of Respondent's case, that his treatment is non-traditional treatment, and whether it's within the mainstream or without the mainstream, which has been an issue raised.

MR. ARMSTRONG: So whether a state accepts it makes it mainstream or not mainstream, is that what you said?

JUDGE DeBUSSCHERE: It's a factor in that consideration, so objection overruled.

Q. Are there any states that specifically sanction EDS, the use of these devices for EDS?

A. Yes, there are a number of states, specifically Florida and Massachusetts, allow the use of EDS or EAV, as it's also called by the German designation, or it's called German Electroacupuncture. They allow the use of the instrumentation under the acupuncture regulations.

Other states, particularly Arizona and Nevada, allow the instrumentation under homeopathic regulations.

Q. In those states they allow homeopathy, in other words?

A. Yes, they do.

Q. Now, in the United States, as we have [2852] learned so far, it's true, isn't it, that the FDA will not clear a device for Electrodermal Screening; is that correct?

A. That is correct.

Q. Has the FDA cleared devices other than yours, as galvanic skin response devices?

MR. ARMSTRONG: Objection, Your Honor.

MR. BISHIN: He's an expert in this field, Your Honor.

MR. ARMSTRONG: He just made the statement that the FDA has cleared, the FDA cleared EDS, and then he made an answer, and he said other than your device, has the FDA cleared. That's not been established.

MR. BISHIN: No, no, other than his device, has the FDA cleared galvanic skin response devices.

JUDGE DeBUSSCHERE: I'll allow that question, if that's the objection. Go ahead.

Q. Has the FDA cleared galvanic skin response devices, computerized galvanic skin response devices, that are used in the health care industry, other than clearing yours?

MR. ARMSTRONG: Objection, Your Honor.

JUDGE DeBUSSCHERE: Overruled. Can you [2853] answer that?

A. I'm not sure. Do you mean other EDS devices?

Q. Yes, manufactured by others, not you.

A. Yes, they have.

Q. About how many others have been cleared?

A. I know of three other companies.

MR. ARMSTRONG: All right. I renew my objection, Your Honor, to the whole line of questioning regarding the galvanic skin response devices. The objection is for vagueness.

JUDGE DeBUSSCHERE: Your objection is on the record, and so you have that, so you don't need to make, in regards in your objection to vagueness on galvanic skin response devices and EDS devices, your objection to vagueness is on the record. You have that.

It's part of the record. You don't need to make an objection every time the question is asked. Thank you. Next question.

Q. These are the devices. Are you familiar with what the FDA has cleared them for?

A. Yes, I am.

Q. And what has the FDA cleared those other devices for?

A. Some devices for biofeedback, and one device [2854] for patient data acquisition.

Q. Okay. Now these particular companies, however, they are devices used for Electrodermal Screening by practitioners, is that correct?

A. Yes.

Q. Now has the FDA ever taken any action against those companies that distribute, the ones that have the clearances that distribute these devices?

MR. ARMSTRONG: Objection, Your Honor. What the FDA has done with another company is not relevant to this hearing, because we're talking about the LISTEN device and his company. We can talk about crimes in other countries all day long. No relevance here. Waste of time.

JUDGE DeBUSSCHERE: There has been questions on direct with Mr. Ogden of what FDA action, whether or not they take action or not action –

MR. ARMSTRONG: Against this company.

JUDGE DeBUSSCHERE: – with regards to the process procedure and action, what the FDA has done, so it's relevant in that respect.

MR. ARMSTRONG: Since we're not talking about federal violations any more, it's still not [2855] relevant.

JUDGE DeBUSSCHERE: Your objection is overruled.

MR. BISHIN: Would you read back my question, please.

(The pending question was read.)

A. I have not heard of any.

Q. Now, would you expect to hear, if they had?

A. It's a small industry, yes.

Q. Now has the FDA ever taken any action against you for distributing these devices?

A. None.

Q. Have they ever sent you any regulatory letters telling you to cease and desist?

A. None.

Q. Have they ever brought any lawsuits against you?

A. No, they have not.

Q. Have they ever called you and said we don't think you should be doing this?

A. No.

Q. Do you have a history with the FDA?

A. Yes, I do.

Q. When did you first have contact with the FDA?

[2856] A. The first contact would have been about 1990, somewhere in the early 90s, when we were setting up an IRB with the LISTEN system, and even though we received information that it was a Non-Significant Risk device, we submitted information to the FDA all about the IRB, and about the actions of the IDE.

Q. Okay, and IDE means Investigational Device Exemption?

A. Yes.

Q. So your first contact with the FDA was in the 1990's, you said?

A. Yes.

Q. Have you had contacts with the FDA since the early 90s?

A. Yes. I have communicated with them during submissions that I have had. I have been to the FDA in their building in Rockville, Maryland, meeting

with department heads, and with other staff that they had.

Q. And about how much time would you say you have spent dealing with the FDA over the last, I guess it's 11 years, something like that?

A. Yes. In any given year it probably represents four months of my work.

[2857] Q. Let's go into, and what has been the subject of your contacts with the FDA?

A. The subject was because of submissions.

Q. What particular product?

A. With the LISTEN system and with the Digital Conductance Meter.

Q. And also the Orion?

A. With the –

MR. ARMSTRONG: Objection, leading the witness, suggesting the answer.

JUDGE DeBUSSCHERE: Objection sustained, leading the witness.

Q. Have you also had contact with the FDA regarding the Orion?

A. Yes, I have.

Q. Is that the extent of the subjects of your contacts with the FDA?

A. Yes.

Q. So is it fair to say that basically you have been in contact with the FDA regarding these kinds of products since 1992?

A. Yes.

Q. Let's talk about the beginning of your relationship with the FDA, FDCA in 1992, say that had to do with Investigational Device Exemption.

[2858] A. Yes.

Q. Let me ask you this before, let me, since you have mentioned that, call something to your attention here. I believe this is Respondent's Exhibit 4 on page ten. Would you take a look at Respondent's Exhibit 4, please.

A. Yes, I have looked at this.

Q. What is Respondent's Exhibit 4?

A. My company sent the FDA a letter in, as it states, February of '92, requesting advice information on the Investigation Device Exemption, particularly for whether the instrumentation was Non-Significant Risk or not.

Doctor Blackwell responded back that it was a Non-Significant Risk device.

Q. What's the significance of being a Non-Significant Risk device, why would you want to know that?

A. The IRB, the Institution Review Board and processor manufacturer come under the abbreviated regulations for conducting the research, instead of what are referred to as a formal study.

Q. What is the significance of that, for the Panel?

Q. Well, basically with a Non-Significant Risk [2859] device you don't even have to tell the FDA that you exist. Now we knew that beforehand, because the IRB that we had set up had already defined the instrument as a Non-Significant Risk, but we still wanted to contact the FDA and be able to see what their –

Q. My question has to do with what is the significance of abbreviated, whatever it was you said, abbreviated requirements described in Section 812.2 B of the IDE regulation, what is the significance of that?

A. The importance as a Non-Significant Risk device, it's considered it's not harm.

Q. Thank you. Let me ask you this: When you have a determination that it's a Non-Significant Risk, do you have to have the FDA actually approve your investigation and research?

A. No, you do not.

Q. Do you have to tell them anything about the research?

A. No, you do not.

Q. When does the FDA get involved, then when you have abbreviated requirements for an investigational device?

A. When you submit your PMA, your premarket approval information to the FDA.

[2860] Q. In other words, after you finish doing your research, and you're ready to ask for an approval?

A. That's correct.

Q. At some point – let me just go back. I neglected to ask you something general about these devices. You testified that the FDA does not clear these devices for Electrodermal Screening.

MR. ARMSTRONG: Objection.

MR. BISHIN: That's a preface to a question. It's already been testified to.

JUDGE DeBUSSCHERE: Overruled.

Q. Although the FDA does not clear them, what is the position of other countries with regard to these devices?

A. The instrumentation is accepted in many other countries.

Q. Is it accepted by government authorities for EDS use?

A. Yes.

Q. Can you give us some of the countries in which that's true?

MR. ARMSTRONG: Objection, Your Honor. Objection to this one, and I already objected to the last question. It's not relevant, not needed. There's a lot of products and devices accepted in [2861] Korea, not here, a lot of things accepted in other countries.

It's not relevant to determine if Doctor Ames treated Patient 1 with a LISTEN device, not even related to allergy treatment. This is getting way into a historical. Waste of time, not relevant, and won't help the Panel.

JUDGE DeBUSSCHERE: Mr. Bishin, do you want to respond?

MR. BISHIN: This is related to the reasonableness of the decision to use this device.

MR. ARMSTRONG: Because other countries accepted it?

JUDGE DeBUSSCHERE: It goes to the issue of non-traditional treatment, which is Respondent's under RCW 18.130.180(4). Objection overruled.

Q. Can you tell us the names of some of the countries that allow these devices to be marketed as EDS devices?

A. European countries, African countries, Australia.

Q. Can you tell us some of the European countries?

A. Germany, France, England, Spain, Italy, Greece.

* * * *

[2870] hear?

MS. PAXTON: Yes, that's-what I wanted to hear, Thank you.

Q. All right. Now Exhibit 1 is dated – you don't have it in front of you any more. This was sent on August 18th; is that right?

A. Yes.

Q. Now prior to this submission in August of 1992, did you make an earlier submission for a 510 K clearance in that year?

A. Yes, I did.

Q. Do you remember when you did that?

A. I did it in January of '92.

Q. And what was the, what was that for?

A. That was for the LISTEN system.

Q. And what happened to that particular submission?

A. The FDA responded with some questions. I responded back. Then the FDA rejected that submission because of acupuncture claims.

Q. Can you state a little bit more, a little bit more elaborately what the nature of their objection was?

A. Just the information on acupuncture, that they had basis points.

[2871] Q. What particular claims did they say that they wouldn't be able to clear?

A. Just the simple connection with acupuncture.

Q. Whether it could be used in some way for acupuncture; is that what you're saying?

A. Yes.

Q. Then after that clearance was rejected, why did you submit this clearance for the Digital Conductance Meter?

A. It was after that I had conversations with the FDA in the submission of the LISTEN 510 K. I asked what things could be done for submission, and they said I needed to exclude the acupuncture claims, and submit the instrumentation without the acupuncture claims.

Q. And is that why you submitted the DCM submission?

A. Yes.

Q. Do the people you submitted it to, were they the same people you had been talking about with the LISTEN?

A. Yes.

Q. Was your purpose in getting the DCM clearance, was that to, in effect, clear the LISTEN?

A. It was to clear the ohmmeter and the [2872] capability for the LISTEN system without the acupuncture claims.

Q. Was it to clear the LISTEN system?

A. Yes.

Q. Was it in order for you to be able to market the LISTEN system?

MR. ARMSTRONG: Objection. He asked the question and answered it.

MR. BISHIN: No, I changed it –

JUDGE DeBUSSCHERE: Overruled. It's not asked and answered. What was your question? Restate it.

Q. My question was did you seek the DCM clearance in order to be able to market the LISTEN device?

A. Yes, I did.

Q. And after you obtained the DCM clearance, did you market the LISTEN device?

A. Yes, I did.

Q. Were the people that you were dealing with at the FDA aware of this?

A. Yes.

Q. Had they ever complained about that?

A. No.

Q. Now, in making your submission to the FDA [2873] about the Digital Conductance Meter, that second 510 K submission, tell the Panel what it was that you actually submitted, what were the components of the device that you submitted to the FDA?

A. The components were the galvanic skin response, ohmmeter circuitry, the computer, the software and the signal generator.

Q. Okay, and the signal generator, was any question ever raised about that at all, by the FDA?

A. Yes.

Q. What question was raised?

A. The question was what were the signals, what did they look like. I had to get a specific oscilloscope to be able to print out all the square wave, sine wave and triangle wave for the FDA, and submit that as an addendum.

Q. Did they approve that?

A. Yes.

Q. So they accepted the DCM with the signal generator at this point; is that correct?

A. That's correct.

Q. Now what exactly does the signal generator do?

A. It sends out a signal just like music, but in this case it doesn't go to speaker, it just goes [2874] to a probe antenna device.

Q. You say it sends out a what again?

A. An electromagnetic field is what it generates.

Q. What kind of electromagnetic field does it generate?

A. A pulsing.

Q. And it's just one electromagnetic field? Tell the Panel how the signal gets generated.

A. The signal is based on a digital pattern, zeros and ones in this particular, zeros and ones, and when they come out they make different patterns, different electromagnetic fields.

Q. Are you saying the signal generator will generate different electromagnetic fields?

A. Depending what the operator does, yes.

Q. How many different electromagnetic fields can the signal generator generate?

A. It's a computer, so it can generate just about anything that somebody would request.

Q. What do you mean by just about anything?

A. Any kind of pattern, a variety of different patterns.

Q. There is more than one kind of electromagnetic field, is that what you're saying?

[2875] A. The electromagnetic field is the same. The pattern can be different, there are multiple different patterns.

Q. Patterns of what?

A. The patterns can simulate foods, they can simulate products, they can simulate a number of different things that are in the environment.

Q. Can you explain to the Panel a little bit about what you mean by simulating, for example, food?

A. The concept of the signal is it simulates things just like a homeopathic product, that it has the signal for the particular product.

Q. Now, this device can be used for Electrodermal Screening; isn't that correct?

A. Yes.

Q. Is it also used by NAET practitioners?

A. Yes, it is.

Q. Is it used in the same way it's used by EDS people?

A. No, there is a different protocol.

Q. Does the signal generated have a special role for NAET practitioners?

A. Yes, it does.

Q. What is that role, as you understand it?

A. It's to be able to output a signal to see if [2876] it will, in this case, provoke work with applied kinesiology.

Q. Now, I want to call your attention again to the clearance for the Digital Conductance Meter.

MR. TENNIS: Exhibit?

MR. BISHIN: I'm just trying to find it. It should be the 1996 document, Exhibit 2, page three.

I want you to read to the Panel the, and for the record –

MR. ARMSTRONG: Objection. The Panel can read for themselves.

MR. BISHIN: This is for the record.

JUDGE DeBUSSCHERE: Let's see.

MR. BISHIN: I'm going to ask a question about this, Your Honor.

JUDGE DeBUSSCHERE: Okay, objection overruled, but you can renew your objection if he tries to repeat it.

Okay, go ahead, Mr. Bishin.

Q. I'll read the bottom paragraph to you, because I want to ask you what this means.

"This letter will immediately allow you to begin marketing your device as described in 510 K premarket notification. An FDA finding of

* * * *

[2879] A. Yes.

Q. What is the concern, that the public might be misled by a clearance?

A. Yes. The documentation says so, and they have told me in person.

Q. So therefore any materials that you sent to Doctor Ames would not reference the clearance; is that correct?

A. That is correct.

Q. Now I want to talk to you a little bit about this particular device, and its various uses. Is there any danger, any physical danger in using this device?

A. No, there is not.

Q. And it does use electricity and it does emit these electromagnetic fields and patterns, as you have just indicated. That might sound to lay people

as if it would be dangerous. Can you tell us why it isn't?

A. When you do the submission to the FDA, the FDA has no specific electronic standards. You have to go to other groups, underwriter laboratories, electronics, electrical engineers, called the I triple E. You have to use circuitry chips that have been tested so that they have the isolation that you [2880] need.

The particular circuitry in this was developed over 10 years ago, I believe, and the chip that was available then is called an isolation amplifier chip, and it was submitted to the FDA. I had to submit the electronic literature, the underwriter laboratory, the I triple E standard that it fell under, and the FDA gave clearance for this instrumentation to touch the skin.

Q. Has anybody ever complained about being harmed by this device?

A. No.

Q. You never received a complaint from a customer?

A. No.

Q. Have you ever heard of customers of any other manufacturer of these types of devices, complaining that they were injured by this device?

A. No.

Q. Have you ever heard of any lawsuits for product liability being brought because of this device?

A. No.

Q. The signal generator, does it, how much energy or power does it emit when it's being used in [2881] the way you described earlier?

A. Less than the actual ohmmeter circuitry.

Q. And the ohmmeter circuitry is what?

A. It can be up to five volts and eight to 10 microwaves.

Q. And the FDA never raised any concern about the safety of this device; isn't that correct?

A. That's correct.

Q. That's why you have a Non-Significant Risk determination; is that correct?

A. That's correct.

Q. Now, just to give you a little about the history, you testified to submitting a device to the 510 K pre-market notification for the device under the name LISTEN, and you testify that it was rejected, and then you went to the DCM, it was accepted, so you started marketing the LISTEN.

You're not marketing the LISTEN any more; isn't that correct?

A. That's correct.

Q. You're marketing these devices that you mentioned to us before. Tell us a little bit more, fill in

the picture of what happened there, why did you stop marketing the LISTEN device?

A. In 1997 a corporation came in and requested

* * * *

[2883] Q. Now, drawing your attention to the device that you identified before, the one to your left, which you have called the LISTEN, have you ever been contacted by the Washington State Department of Health, or any representative of the Washington State Department of Health, with respect to that device?

A. No, I have not.

Q. So they have never inquired, tried to find out any information from you about that device; is that correct?

A. That's correct.

Q. Okay. Now were you ever contacted by anybody from the office of the Attorney General in the State of Washington with respect to that device which I'm referring to, the LISTEN device to your left?

A. No.

Q. Has anybody from any governmental agency or any employee of the State of Washington, as far as you know, ever attempted to find out anything from you about how this device functions?

A. No.

Q. Has anybody from the State of Washington, employed by the State of Washington, as far as you know, ever attempted to find out if this device poses [2884] a risk to anyone?

A. I don't know.

Q. So you don't know whether they have or not?

A. I don't know whether they have or not.

Q. I'm asking if they have contacted you.

A. No, they have not contacted me.

Q. Have you ever had a report that anybody at your company was contacted by anybody from the State of Washington with respect to this device?

A. No.

MR. BISHIN: I'm going to rest at this particular time with this witness.

JUDGE DeBUSSCHERE: Let's go off the record for one minute.

(Discussion off the record.

JUDGE DeBUSSCHERE: Back on the record. Mr. Armstrong, cross-examination?

MR. ARMSTRONG: Yes.

JUDGE DeBUSSCHERE: Do any of the Panel members need a break? We'll just go off the record for one minute.

(Discussion off the record.)

JUDGE DeBUSSCHERE: Okay, we're back on the record. Mr. Armstrong, cross-examination?

MR. ARMSTRONG: Yes.

* * * *

[2891] A. They weren't different, no.

MR. BISHIN: Objection.

Q. Well, I asked did you submit the exact same thing, and you said no?

MR. BISHIN: Object to the vagueness of it. You included labeling in there, and included some other things.

MR. ARMSTRONG: Well, there's a lot that goes in 510 –

JUDGE DeBUSSCHERE: Objection overruled. The question has been answered. Your next question.

Q. You answered it, correct?

JUDGE DeBUSSCHERE: No, he answered did you exhibit the exact same thing. He said no. Next question.

Q. For the DCM submission in August you submitted it, what was the labeling claim for that submission?

A. Biofeedback.

Q. Was it submitted for anything else, as in allergy treatment?

A. No.

Q. Allergy diagnosis?

A. No.

Q. Curing of any ailments?

[2892] A. No.

Q. Can the device that you submitted in August 1992, the DCM, can it be used to diagnose allergies, food allergies, used to diagnose food allergies?

MR. BISHIN: I'll object to the question's vagueness. Used by whom, and what does the word "can" refer to? Is he asking him a question about whether or not it has the capability of performing a health care function.

It's a little bit, depending on what the meaning of the question is, it may be calling for an answer from him that he can't give, because he is not a health care provider.

On the other hand it's a –

MR. ARMSTRONG: That's a good point.

JUDGE DeBUSSCHERE: I'll sustain the objection. Just restate your question, Mr. Armstrong.

Q. Mr. Clark, can the DCM which you submitted in August 1996, is it capable of presenting a medical diagnosis for food allergies?

A. No.

Q. Are you a medical doctor?

A. No.

Q. Are you able to tell us what a medical [2893] doctor could tell us regarding a medical diagnosis, are you able to provide a medical diagnosis to the Panel here today?

A. Am I?

Q. Yes.

A. No.

Q. The LISTEN device that was submitted in January 1992, does that machine have the capabilities of providing a medical diagnosis for allergies?

A. No.

Q. How about curing allergies?

A. No.

Q. Does the LISTEN device or the DCM, which you submitted both of them, and so you know the capabilities of both, do they have the capabilities of providing acupressure to human skin, can those devices perform acupressure on the human skin?

A. Acupressure, as a mechanical –

Q. Yes.

A. No.

Q. So they can't provide acupressure?

A. That's correct.

Q. The LISTEN device that was rejected in 1992 because whatever requirements were not met, did you change any of the functions or capabilities, and [2894] re-submit it in August?

A. No.

Q. Or did you have another whole different product that you re-submitted in August?

MR. BISHIN: He answered the question. He said no.

MR. ARMSTRONG: I asked a different question, and I don't have the answer yet.

JUDGE DeBUSSCHERE: Okay, that question stands. You didn't get a chance to complete your second question. Complete your next question, and then you can object if you wish, Mr. Bishin.

Q. In August 1992 did you submit a new or different or modified device for submission for your 510 K, new or modified?

A. The acupuncture claims were removed. That's the difference.

Q. So you just changed the claims?

A. That's correct.

Q. There were no specification differences?

A. That's right.

Q. No software differences?

A. That's correct.

Q. No electronic differences?

A. That's correct.

[2895] Q. The voltage that it output was the exact same?

A. Yes.

Q. So you just took the same device, took off the claims, and it was approved, and it was approved for what?

A. It was cleared.

MR. BISHIN: Objection. Asked and answered.

JUDGE DeBUSSCHERE: Overruled, You can answer it. Restate the question.

Q. What was the DCM that was submitted in August 1992, what was it cleared for?

JUDGE DeBUSSCHERE: That was asked and answered.

MR. BISHIN: That's why I objected.

MR. ARMSTRONG: That's why you objected.

Do you own the patent for the LISTEN device?

A. No.

Q. Who has the patent for the LISTEN device?

A. Nobody has the patent.

Q. It's not patented?

A. No.

Q. How about the DCM?

[2896] A. No.

Q. There's no patent for the DCM?

A. No.

Q. How about the new products, the Orion?

A. There are applications for the Orion that I received a patent for in the year 2000, for outputting signals for treatment with additional hardware, including lasers, infrared and other modalities.

Q. Would that make it a different product than is sitting right here?

A. Yes.

Q. So you have received a patent for a device that's not sitting in this room?

A. Yes.

Q. This device that's sitting in this room, which we're calling the LISTEN, is not patented?

A. Yes.

Q. When the FDA cleared the DCM device, did they clear it for EDS, Electrodermal Screening?

A. No.

Q. So it's not cleared for Electrodermal Screening?

A. No.

Q. Even though in use, it has the capability of [2897] Electrodermal Screening, it's not cleared for that?

A. Yes.

Q. Does that mean that practitioners that you sell the device to, that they can use it for Electrodermal Screening?

MR. BISHIN: Objection. Question of law about off-label use.

Q. I'm asking your understanding.

JUDGE DeBUSSCHERE: I ruled that it's a question of law of whether or not, but he's asking here in particular what his understanding is. You can answer the question.

MR. ARMSTRONG: Your Honor, I withdraw the question because it's dealing with a legal

conclusion. I don't want Mr. Bishin to be able to ask about off-label use either. If you're going to allow me to, I'll be glad to allow him to, but I don't want him to answer the question because –

JUDGE DeBUSSCHERE: I said I ruled that the question about what is off-label use is a question of law, but that you can ask this individual about his understanding.

MR. ARMSTRONG: I'll withdraw the question, motion to strike my own question.

JUDGE DeBUSSCHERE: Your statement, you

* * * *

[2922] A. Yes.

Q. Now, you said there are other people selling similar things.

A. Yes.

Q. If I buy one in Germany, is the signal coming out going to be the same for egg?

A. I don't know. So many of the instruments that are out, they're ones that have taken my software. They actually took my LISTEN and incorporated on their system, so those I'm aware of.

Q. How do you learn this, I mean where did you learn that you could transmit egg with a signal, fish with a signal, and how did you decide what the

signals would be, I mean what's the theory or whatever behind it?

A. The theory is I actually had to wait for the full definitions, NIH, and through the patent office, and the patent office stated that by them simulating a homeopathic, and therefore I am putting in a signal that represents egg, for example, and that particular signal simulates having the egg there.

I can go through that process. It's a lot shorter than 10 minutes, but I can give you that.

Q. Well, that's okay. I don't need the process. Probably I don't understand the process [2923] anyway.

What I'm trying to say is there a logic, science, something that's accepted by more than one person, you; is there a dictionary, I mean can somebody else make one like that?

A. Yes, there are other people that if they knew what I knew, the National Institute of Health, Office of Alternative Medicine issued a Panel report in 1993. This was 14 years after I developed it, and they presented in there that non-ionizing, non-thermal, frequency specific electromagnetic fields, can produce a beneficial or a harmful affect.

Q. I understand that. I have done a course in homeopathy myself.

Forgive me, I think I have to be excused for a minute here. I have a pager I have to answer.

JUDGE DeBUSSCHERE: Let's take a five-minute recess, and depending on when you're ready. We'll go off the record.

(A break was taken.)

JUDGE DeBUSSCHERE: We're back on the record. Mr. Clark is testifying.

Doctor Uberoi you were asking questions. Go ahead.

[3019] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent.	)	Docket No. 02-06-A-1012MD DAY 5

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

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CABELL TENNIS, J.D.,
Public Member

Renton, Washington
February 10, 2004

REPORTED BY JEAN ERICKSEN, CCR

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* * * *

[3026] everything that covers that matter, so it's now an opportunity for the Respondent to continue the presentation of his case.

Your next witness, Mr. Bishin?

MR. BISHIN: My next witness is Doctor Ames. Doctor Ames, will you please take the stand.

JUDGE DeBUSSCHERE: Doctor Ames, I know that you were sworn in at the last time we had the hearing in this case, but I would again ask that you be sworn in for today's hearing. Would the court reporter swear this witness in.

GEOFFREY S. AMES, M.D.,

having been first duly sworn, testified as follows:

DIRECT EXAMINATION

BY MR. BISHIN:

Q. Doctor Ames, where were you born?

A. I was born in Methodist Hospital in Dallas, Texas.

Q. How long did you live in Dallas, Texas?

A. Eight years.

Q. Where did you go from there?

A. Richfield, Connecticut.

Q. How long did you live there?

A. Until my junior year in high school, age 17.

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[3036] allergy.

I was amazed. She was also amazed that a simple treatment could cure my weed allergy, where

she also tried immunotherapy for years, and it did not work on her.

Q. Why were you amazed at the cure for weed allergy?

A. Because the standard practice for treating food allergies is just avoidance. It's very hard to cure a food allergy, so most allergists will just say avoid that food.

Allergy shots or sublingual allergy drops have limited success in treating food allergies.

Q. Okay, so that particular sort of a chance encounter, you're saying about NAET, how did that lead you to get further acquainted with the NAET therapy?

A. Well, I did call her office and I looked at her web site to learn more about it.

Q. Who is this?

A. Sorry, Doctor Nambudripad.

Q. All right, so did this person you met at Doctor Rea's center tell you about Doctor Nambudripad?

A. Yes. She gave me the web address.

[3037] Q. So the next thing you did was to go on the Internet and check out the web site; is that it?

A. Yes. Subsequently I took more courses from the American Academy of Environmental Medicine

and the American Academy of Otolaryngic Allergies, and I also met fellow colleagues who had already previously taken NAET Courses.

Q. How did you know that they had taken these courses?

A. I asked them. I said have you ever heard of NAET, and they said, Sure, I have already taken basic and advanced courses. I asked them how does it work, and they said it works fantastic. You must go down there and try it out yourself.

Q. Now, who were these people, these were people who were attending the same courses in allergy medicine, is that what you're saying?

A. Yes. One is Doctor Brownstein, Doctor David Brownstein, an author there in Michigan.

Q. Were they doctors, these people?

A. Medical doctors.

Q. How many doctors would you say you spoke to?

A. Around 20 doctors.

Q. So you talked to about 20 doctors at these various courses about NAET?

[3038] A. Yes.

Q. Okay, and of these 20 that you spoke to, did they all practice it?

A. They all practiced it.

Q. These are medical doctors?

A. These are medical doctors.

Q. So having spoken to them about it, what generally did they tell you besides the fact that they thought it was fantastic; what was fantastic about it?

A. Well, they said it's very quick. Patients don't have to come back for years, and spend lots of money in getting treated. It's very safe. Nobody has ever died from it, it's harmless, there's no side effects, and they said they get fantastic results.

They might not be able to cure everybody of allergies, but it's the best therapy they have ever encountered.

Q. You say "nobody has ever died of it." Why would they mention that?

A. Because just doing a prick test, an intradermal skin test testing for allergies can be dangerous. Say a person is very allergic to peanut allergy, they can actually die from testing, or they could have a severe reaction from immunotherapy. If

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[3042] First of all, did she lecture during the 16 hours?

A. She lectured pretty much the whole time.

Q. Was it really a full 16 hours?

A. Yes.

Q. How much lecturing did she do?

A. She lectured the whole time, except when giving demonstrations and during breaks.

Q. Can you describe her, how she appeared to you, and what your evaluation was of her in the presentation?

MR. ARMSTRONG: Objection, Your Honor, relevance.

MR. BISHIN: I can't hear you, Counsel.

MR. ARMSTRONG: Objection, relevance.

JUDGE DeBUSSCHERE: Overruled.

A. First of all she has a Ph.D. in Oriental medicine. She's a doctor of chiropractic and a trained kinesiologist.

She's very enthusiastic about her approach, because she, herself was allergic to every food in the world except rice and broccoli. For three years all she ate was rice and broccoli.

She had to wear the same blouse every day for three years. She would wash her blouse out each

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[3044] she was saying?

A. She had told us that she had already cured herself of her allergies, and that she had already

treated thousands of people, and cured them of their allergies.

She had a symposium once a year for people that have taken the courses to come back and give their case histories.

Q. Did any of the physicians or health care practitioners of this course or other courses you went to, ever verify or support what she was asserting?

A. Yes, definitely.

Q. That's what they were referring to when they talked about fantastic results?

A. (Nods head.)

Q. Is that correct?

A. Yes.

Q. You have to answer the question verbally.

So you went to these courses, and you said you were still skeptical at that particular time. Did you decide to pursue an interest in NAET at that time?

A. Yes, I did. I decided I would choose five of my worst allergic patients, and give them free

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[3051] kinesiology, but it was all new to me. I had never had any kinesiology courses before, and I was still skeptical.

Q. Now, have you found any evidence that supports the idea that this works?

A. Well, I have literally two of the strongest people in the entire world as my patients. They're the world power lifters in their age categories. They actually hold world records.

I can tell them to use all their might, and put an allergen in their hand, and their arm will go totally weak. I also did this with a Kennewick police officer in his 20's. He could definitely out power me, and –

Q. What was his dimensions?

A. He was around 220 solid muscle, and I found out he was allergic to eggs. It made his arms totally weak with just one finger.

Q. What do you mean by one finger?

A. I just used my index finger to pull his arm down. He couldn't hold his arm up.

Q. When did that happen, when did these experiences occur?

A. Well, they happened in the past by at least two power lifters. I actually saw them in December.

[3052] Q. Now, at the beginning you weren't seeing these power lifters when you initially encountered NAET, were you?

A. No.

Q. What was the evidence at the time you started to take this seriously?

A. Well, empirical evidence. I would do it on my patients. I'm not trying to hurt their arm. I only use about 10 pounds of pressure. I'm not trying to overpower the patient, or the patient is not trying to overpower me. Every time I put the allergen in their hands, their arms would go weak, and I would correlate that with blood testing.

When the blood test was positive, at the same time the arm would go weak, when I test them for that allergen. I had a very good correlation of blood testing.

Q. Tell us how you did that, to assure that you weren't in some way affecting your little test of its effectiveness?

A. Well, I always try to do blood testing first, unless patients can't afford it. Let's say somebody has a very strong reactivity to a food, then I'll test different things that they might not be allergic to, for instance, calcium or salt or vitamin

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[3066] moment.

Can I show this to the witness, Your Honor?

JUDGE DeBUSSCHERE: Yes.

Q. Showing the witness Exhibit 5. I believe it's Exhibit 5. Yes, Respondent's Exhibit 5.

Will you take a look at that, please?

A. Yes.

Q. Does that refresh your recollection about when you took the UCLA course?

A. Yes.

Q. So about when was that?

A. November '97 to May '98.

Q. Had you bought the device by that time?

A. Yes.

Q. You had bought it by then?

A. Yes.

Q. So it was somewhere between the NAET course and this course that you bought the machine?

A. Yes.

Q. When did you have these conversations with Mr. Clark, how many months before you bought the LISTEN device?

A. Approximately three to four months. I would call him up about once a month and talk to James Clark or his brother Bill Clark, and ask questions [3067] about these machines.

Q. Would that have been after or during or before the first NAET course?

A. That would be after the first NAET course.

Q. Okay. Why did you take the UCLA acupuncture course, having had the NAET course, why did you feel you needed that course?

A. Well, prior to medical school I had the opportunity to learn acupuncture as a non-practitioner in Marin County, California, and that got me interested in going to medical school, so acupuncture has always been of interest to me.

I understood that, according to acupuncture theory, that diseases could be caused by a blockage of energy in a meridian, and an acupuncturist, over time, could cure allergies with acupuncture.

I also had patients who were addicted to cigarettes, nicotine, and some pain patients, and I wanted to use acupuncture on these patients.

Q. Why didn't you think that the NAET would take care of that?

A. The NAET can be used to treat smoking addiction, but acupuncture is also another good therapy for that. Sometimes one therapy might not work on a patient, so I wanted to further learn more

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[3076] because some people are not familiar with acupuncture. I don't give them a thorough course on acupuncture theory. I wouldn't have time to see patients if I did that. That might take me an hour.

Q. Okay, but you do tell them something about it?

A. Yes.

Q. What do you tell them, to the best of your recollection; do you have a standard little routine?

A. Oh, yes. I tell them that the theory is that the allergen held in their hand, if you're allergic to it, will close down the acupuncture meridians. The meridians go, the organs and the muscles.

Doctor Goodheart discovered that in 1964 that muscle will become weakened when exposed to an allergen, so then I describe the process that I'll be doing on them, the kinesiology test, which arm I'll be using, et cetera, and then I tell them that I'll be giving you simple acupressure along the back, and that you must stay away from the allergen for 24 hours if there is going to be a cure.

Q. Is that all part of the NAET protocol?

A. Yes.

Q. It is?

[3077] A. Yes.

Q. Now let's turn if we can – let me ask you this: Do you tell these people that this is not a conventional form of therapy?

A. Yes, I tell everybody that.

Q. What words do you generally use?

A. I say this is not a conventional form of therapy, it's a form of acupuncture, but we're not using needles, we're using acupressure.

Q. Do you ever use anything like a written statement of Informed Consent for this?

A. Every patient signs an Informed Consent before getting the first treatment.

Q. What generally does the Informed Consent say?

A. The Informed Consent basically says that, what NAET is, what it does, and basically that it has no side effects.

Q. Does it tell them that it's not conventional?

A. I have to look at it to refresh my memory.

Q. What's the point of it if you're not going to tell them it's not conventional?

A. What's the point of the Informed Consent?

Q. Yes.

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[3090] as Exhibit Number 8.

MR. BISHIN: Could the presiding officer show it to the Panel so they have a chance to look at it. It's not very long.

JUDGE DeBUSSCHERE: I'll have the Panel members look at Exhibit Number 8.

(Pause in proceedings.)

JUDGE DeBUSSCHERE: Exhibit Number 8 has been reviewed by the Panel members, and now Doctor Ames has it before him.

Your next question, Mr. Bishin.

Q. Doctor Ames, tell us when you ask patients to look at this and sign this form that's been marked as Exhibit 8?

A. Right before they get NAET treatments.

Q. Right before they get it?

A. That's right.

Q. Did Patient 1 sign this document?

A. No.

Q. Why didn't he sign it?

A. Because I never treated Patient 1 with NAET.

Q. So you never offered it to him?

A. I offered that he could –

Q. You never offered Exhibit 1 to him?

A. No, I never offered Exhibit 1 to the [3091] patient.

Q. Can you tell us when you – let me ask you this. Have you reviewed your entire chart and file for Patient 1?

A. Yes.

Q. Did you find a signed copy of that Informed Consent form in that file?

A. No.

Q. If you had treated him, would you have expected to find it in that file?

A. Yes.

Q. What is your practice with regard to that?

A. When people come in for chronic fatigue, it takes me so long on the second visit, that I have people get the NAET on the third visit, if they decide to go with NAET.

On the second visit I thoroughly demonstrate NAET to the patient, so they know what they're getting into.

Q. So my question is when would you normally have them sign it?

A. On the third visit.

Q. On the third visit, and this was only the second visit; is that what you're saying?

A. Correct.

[3092] Q. Now, is this a routine of yours, is this a routine that you follow generally, strictly, loosely, what?

A. I follow this routine strictly.

Q. That's sort of your protocol?

A. Yes.

Q. Was that your protocol at the time that you saw Patient 1?

A. Yes.

Q. Now let's go to that second visit, if you would. Could you describe for us what happened at that visit, to the best of your recollection, what you did?

A. The second visit I described what was abnormal in his laboratory values, and how to correct these. I also described to him that he may have food allergies because the RAST test showed positive to different foods, so I said that you could do an avoidance of these foods to see if you feel better, give yourself a re-challenge, since these are not life-threatening food allergies, they're igG food allergies or delayed allergies.

Q. Let me interrupt you. I want to lay a foundation as to just exactly what was going on during this meeting.

[3093] At this particular visit did you have reports from the laboratory about Patient 1?

A. Yes.

Q. And did you bring those to the attention of Patient 1?

A. Yes, the patients –

Q. Yes or no.

A. Yes.

Q. Did you discuss the findings of the laboratory?

A. Yes.

Q. All right. Did you go over each finding?

A. Yes.

Q. You did, all right. Now much time would you say you took to go over the findings from the laboratory?

A. It takes most of the visit.

Q. About how much time would it take?

A. About at least a half hour, up to 30 to 40 minutes.

Q. When you talk about discussing the results, what does that consist of?

A. Explaining, first of all, to the patient what these labs mean, because they have never seen these values, and they don't understand what the labs [3094] mean.

Then explaining what diseases are caused, or can be caused by these abnormal labs.

Q. You mean what disease these may be a sign of?

A. Yes.

Q. Okay, and what else would you be telling them?

A. I would be telling them that we have different ways to correct these. In the future you can do repeated lab tests, and see if they change, and if they do change, your fatigue will probably get better, since these abnormal labs can oftentimes be associated with fatigue.

Q. Now, this review of the lab results is that what you would have started with at this visit?

A. Yes.

Q. And after you had finished doing that review, would you have done anything else?

A. Yes, I thoroughly described the NAET technique. I demonstrated the technique to the patient, like I do with my other patients, so they know what they're getting into, so I don't have to do this on the third visit.

Q. So you say you demonstrated it?

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[3100] A. Yes.

Q. Why would you have done that?

A. Because when I'm demonstrating it, I don't like to get patient's oil from their hands on the probe, so I put paper around it.

Q. I think you testified on cross-examination several days ago, I guess last month, that you always lave the patients take off their jewelry; is that correct?

A. Yes.

Q. And did you have Patient 1 take off his jewelry?

A. No.

Q. Why not?

A. Because he wasn't being treated.

Q. Now Patient 1 told you that – let's see. He testified that you had told him that you didn't need the device any more because, or you hardly needed the device any more because you could now do that it does by telepathy; do you recall that testimony?

A. I recall that testimony, yes.

Q. Okay. Now did you say that to him?

A. No, I never said that.

Q. Did you say anything to him that had any of [3101] the elements of that statement, or that might suggest that to a reasonable person?

A. Well, the only thing I can think of is I tell some people that we can test for psychological allergies or subconscious allergies by saying the word, and sometimes that will provoke a weakness, sometimes that will not provoke a weakness.

Q. Now, it is true that you have testified already that you can do this testing without using the device, right?

A. Of course, yes.

Q. So you don't need the device to do the testing; is that correct?

A. No.

Q. Is it possible you told him that?

A. Yes. I tell almost every patient that I tell them they can bring in real foods or their dog hair or their house dust in a baggy, or their dirt around their house, so I tell all patients that, most patients.

Q. Okay, so to the extent that he thought you were saying that you could do it without the device, that would be true?

A. Yes.

Q. That part of it would be true?

[3102] A. Yes.

Q. Do you think you have any telepathic powers to emit these frequencies?

A. No. Otherwise I'd be able to understand my wife a lot better. I don't have any telepathic powers.

Q. Okay. Let's talk a little about, have you had a chance to review Patient 1's records?

A. Yes.

Q. Is your review sufficient, taken with your memory of it, to have an opinion as to whether he would be likely to have memory problems?

A. Yes.

MR. ARMSTRONG: Objection, Your Honor.

JUDGE DeBUSSCHERE: Basis of the objection?

MR. ARMSTRONG: The basis of the question is whether his memory and the records gives him sufficient to have an opinion on his memory problems.

JUDGE DeBUSSCHERE: What's your objection?

MR. ARMSTRONG: No foundation to establish that the doctor has said anything about memory problems. Now Counsel has mentioned memory

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[3113] The allergies were also causing muscle pain and fatigue.

Q. How did all this affect her life at that point; what was she reporting?

A. Well, it made it real miserable. For someone who has never had allergies, it's hard for them to understand how miserable one can be. She was in muscle pain, she had fatigue and it was just real hard for her to function, sometimes cloudy thoughts from the allergens, and always having to blow her nose.

Q. You say she had muscle pain. Did she have it throughout the day, part of the day, for a few minutes?

A. She would have it every day. It would vary in intensity. Sometimes it might only be a two out of 10, where 10 is the worst pain, or sometimes it might be five or seven out of 10, but every day she would have some muscle pain.

Q. Which particular muscles are we talking about?

A. Most of the muscles in the body.

Q. Most of the muscles?

A. Most of the muscles, that's right. Most of the trigger points typically found in allergy

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[3116] A. Yes.

Q. Now, how would you describe the difference between Patient 3 at the present time, and her

condition when she came to see you about the allergies?

A. She was a happier person. She has more energy, less nasal stuffiness, less generalized muscle pain. She feels the NAET has done this for her.

Q. Now, you didn't use the device to test her, though; is that correct?

A. I have used the device to test Patient 3, but I usually have her bring in samples from around her property and environment, little bags. We test new pollens that are arriving in the spring, and so forth.

Q. All right, let the ask you this: As the presiding officer indicated, the number of patients we were able to call was limited by the presiding officer. If you had been able to call all the patients who have done well with your therapy, how many would you have called?

A. I would have called hundreds, at least hundreds. I have treated at least hundreds of patients many times with NAET, with great success.

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[3119] A. Utah.

Q. After you received it, did it ever leave your office?

A. Yes. I brought it home once, and just kept it there while I was studying how to use it, since I'd rather study there than at my office.

Q. You never gave it to anybody?

A. No.

Q. You never sold it to anybody, did you?

A. No.

Q. You already testified you never charged for its use?

A. No, I never charged ever for the use of this machine.

Q. And you indicated before that when you do the NAET, sometimes you use it and sometimes you don't; is that correct?

A. That's right.

Q. When you don't use it do you charge less than you do when you do use it?

A. No.

Q. You charge exactly the same price?

A. Exactly the same price.

Q Have you ever had any problems with the device?

[3120] A. No.

Q. Did it ever cause anybody to have a shock, or anything of that sort?

A. No.

Q. Has it ever occurred to you that it might pose some kind of a danger to a patient?

A. No.

Q. Why not?

A. I talked to Jim Clark. He said that he was working with the FDA, and has been working with the FDA, and his machine is legal to sell to practitioners, doctors.

I can't feel any current going through this machine, and none of my patients have ever felt anything.

Q. Just give me a moment. I'm pretty close to the end here. Oh, let's talk a little bit about ham. You recall that Patient 3 said that you apparently tested her by just saying the word ham; is that correct?

A. That's correct.

Q. Would you describe that event to the Panel so we can get that issue fully covered.

A. Sure. I said the word ham, and I did a kinesiology technique, and her arms went weak. In [3121] the advanced course in NAET we –

Q. Just a moment, before you get into that. Why did you say the word ham?

A. Because I wanted to see if she had a subconscious or psychological allergy to ham.

Q. Why did you think of the word ham?

A. Because she had eaten ham the prior night, as well as a few other foods, and she had an allergic reaction, she thought she was allergic to something she had eaten the night before.

Q. So she actually came to you with that suspicion?

A. Yes.

Q. All right, and what was the reaction; do you recall, to the ham?

A. She tested physically allergic and psychologically allergic to ham.

Q. What was her actual reaction that brought her into your office?

A. I can't recall the exact symptoms that she had.

Q. Okay. so in any event, you took a history; is that correct?

A. Yes.

Q. You asked her what she had eaten?

[3122] A. Yes.

Q. She reported that one of the things she had eaten was ham; is that correct?

A. Yes, that is correct.

Q. So why did you test her with the word ham?

A. Because when I took the advanced course Doctor Nambudripad told us that sometimes people have a psychological allergy to a food, and you can say the food out loud, and the arm will go weak. Since it only takes me a split second to say ham, I might as well test for it, and her arm did go weak.

Q. Why did you say ham rather than use the device?

A. I did use the device, and she tested positive for ham on the device.

Q. Was that after you said ham?

A. No. I tested her for the physical allergy to ham first using the device. Then I tested her for the psychological or subconscious allergy saying the word ham after using the device.

Q. Now you can continue your answer about why you did this.

A. Well, to be real thorough. Some people can have a subconscious allergy to something, say for instance Patient 3 ate ham when she was a little [3123] child and threw up, or had some kind of allergic reaction, or maybe it wasn't even ham, but she associated ham with some other food, and she felt sick afterwards, so she may have been yelled at by her father while she was eating ham. Sometimes that can get imprinted on the mind as an emotional allergy or a subconscious allergy, so when one says the word, you can evoke a weakness.

Q. Are you telling us something that you were told by Doctor Nambudripad?

A. This is what we were told and taught in her advanced course.

Q. Did she have any evidence to support this?

A. She had empirical evidence. She doesn't have the double blind studies, or anything like that.

Q. Did she do any demonstrations that supported this?

A. Yes.

Q. She did?

A. Yes.

Q. Do you recall any of them?

A. I can't recall the exact foods, but she did demonstrate in class.

Q. Is there any scientific evidence that saying a word can have that kind of psychological affect on [3124] people?

A. Yes, of course there is.

Q. How?

A. There's lie detectors. When, say a child was molested as a youth, you can say the word molestation, or name the person that molested the child, and get a response on the lie detector, which is

actually a galvanic skin response machine, and that will actually influence the acupuncture meridians.

Q. Did you treat Patient 3 for the ham?

A. Yes.

Q. Did she ever report that same reaction again?

A. No.

Q. Did she eat ham after that?

A. Yes.

Q. She did, okay. Just for the record would you tell us a couple of the more dramatic results that you have gotten from your therapy with life-threatening allergies.

A. I had a man that had a life-threatening allergy to fish, all fish, and he was real frustrated, because he used to fish with his son all the time, and he couldn't even take the fish off the

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[3137] did not know anything about FDA law, clearance or approved or registered, anything like that.

Q. Didn't you say earlier today in your testimony that you wouldn't have a machine in your office if it wasn't FDA-approved?

A. I wouldn't have a machine in my office, I believe, that wasn't FDA-cleared, I said.

Q. Cleared could be what you said. What's the difference between registered and cleared?

A. I don't know the definition of this, I'm sorry. These are legal terms. I'm not an expert on this.

Q. What did you mean when you said FDA-registered; in your mind, what was your understanding?

A. Jim Clark had told me that the machine is approved to sell to doctors, and he has never had any complaints from the FDA, and he was allowed to sell this machine to doctors. That's what I meant by that, when I wrote this letter.

Q. And you believed it?

A. I believed Jim Clark, yes.

Q. Do you rely on most of the statements, how about everything; Mr. Clark has been open and honest with you about his machine, correct?

[3138] A. Yes.

Q. And you rely on the information that he gives you, correct?

A. Yes.

Q. You also testified earlier you consulted him, after you got the machine, you consulted him often, to try to find out questions about the machine, right?

A. No, that was before I bought the machine.

Q. Oh, before you bought the machine.

A. I consulted with him.

Q. After the machine you didn't call him up and ask questions, periodically?

A. No. I sent my nurse to one of his courses to learn how to use the machine. I didn't have any complaints about the machine. I had no reason to call him.

Q. Well, maybe I misunderstood. I thought earlier you testified that you called him maybe once a month, called him up constantly and –

A. You did misunderstand me, you didn't hear me. I said I called him before I purchased the machine once a month.

Q. About how many times did you call him, if you can remember?

[3139] A. Around three times.

Q. About three times, all about the machine and its operation, or some other purpose?

A. Well, I wanted to find out his dealing with the FDA, I wanted to see how well the machine works, how other people were satisfied, and different questions like that.

Q. Now, as far as investigating, do you have devices in your office, you have already testified that you do a thorough research and protocol to increase

the safety of your patients when you're doing treatments.

How about the devices that you use, medical devices, electronic devices, what type of thorough examination do you conduct to ensure that those devices are safe for your patients?

A. Well, basically I don't use many devices. I use vials and needles. I have an auto-plate machine, and I don't really use, I have a tongue depressor. I don't really use any big devices.

Q. What about the device that you had last time. It was a hand-held device, and looks like some tongs?

A. Right.

Q. What about that machine?

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[3155] later, so that clarifies that. Thank you,

When this all started and the Department started to question you after Patient 1 had put in the Complaint regarding the LISTEN device, why did you just not quit using it, the whole thing?

A. Why didn't I quit using the LISTEN device?

Q. Why didn't you quit, and say I won't use it?

MR. BISHIN: I have to object to this. This goes to what the Department told him, what letters were sent to the Department, what he responded to

it. The question assumes that there was a focus in the Department's investigation on the machine.

I can understand why Miss Paxton would have thought that was the case, but it's an assumption.

MS. PAXTON: But we're talking about the LISTEN device.

MR. BISHIN: We're talking about it now, but that's not what he was led to believe they were most concerned about when the investigation started. That's the problem.

You're going back to the history of this whole thing, and you're assuming what was going on during the time of the, well, I guess you're talking

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[3156] about when the investigation was going on, that's correct, isn't it?

MR. ARMSTRONG: May I respond?

MR. BISHIN: You're assuming what was said in that investigation.

JUDGE DeBUSSCHERE: Objection noted. Mr. Armstrong, your response?

MR. ARMSTRONG: I don't have a clue what Mr. Bishin is talking about, but my objection is he's mischaracterizing what the Panel member is assuming. That's improper. He has no clue.

JUDGE DeBUSSCHERE: I'll overrule the objection, and you can ask the question.

Do you remember what the question was, Doctor Ames?

THE WITNESS: No.

Q. (By Ms. Paxton) In the beginning, when you were made aware there was a problem, or at least someone thought in the Department there was a problem, because you were using the LISTEN device as part of the problem, why didn't you say okay, I'm going to quit using the device?

A. In the very beginning I wasn't aware that I had a problem using the device, from the statement of charges. Once I know the statement of charges, I knew [3157] that the LISTEN machine doesn't harm anybody, it doesn't hurt anybody, it's perfectly safe. It facilitates my practice.

If I use vials I might only be able to test 50 percent of the allergies. If I use the machine I can test more allergens and help that patient more, screen more allergens using the machine, so it really saves my practice time.

Q. Okay. When you got the LISTEN device, and you testified that it came with an operating manual, but basically nothing else?

A. Bill of purchase.

Q. Okay, bill of purchase. Did you ever wonder why it didn't come with any other piece of material that would explain risk or benefit?

A. No, I never wondered that.

Q. Do you wonder it now?

A. No.

Q. Why not?

A. Because when I contacted Jim Clark a few times, he told me that he works with the FDA and he's allowed to sell this machine, and he has no problems. The FDA has never been sued by, the FDA has never told him that he can't sell the machine.

Q. So am I understanding you to say therefore

* * * *

[3167] positive kinesiology test.

With a psychological or subconscious allergy, we say the word out loud and in some patients their arm goes weak. We're taught in the advanced course in NAET that this is how we test for psychological allergies.

Q. How do you know this to be true?

A. Doctor Nambudripad has been doing NAET for many years, and she has many case examples on this, and I took her word for it.

Q. So it's more anecdotal information rather than scientifically-based?

A. Yeah, it's more anecdotal or empirical, but I could see how it worked in the lie detector example this morning, AND how different words can influence the lie detector. People can call you a bad name or something, and all of a sudden you get a lot of nervous responses, so I could see how it could work.

I have never really done a lot of research on this. It only takes me a fraction of a second to say the word out loud. She taught us to do this in the advanced course, so I do it.

MS. PAXTON: Thank you, Doctor.

JUDGE DeBUSSCHERE: Doctor Uberoi, you

* * * *

[3169] Q. Okay –

A. I'm not going to have food in my office.

Q. So it's a kitchen area in the office?

A. Yes.

Q. And it's not an office in the home?

A. It's not an office in the home, no.

Q. The nurse, do you employ an R.N. L.P.N., the nurse who went to learn this machine?

A. She was a registered nurse.

Q. R.N.?

A. R.N.

Q. What was her role in learning the machine, what was she going to be doing after the training on the machine?

A. Originally I wanted her to basically teach me how to use the machine, until I had time to go in there and take a course myself. I knew I wouldn't have time to take a course right away, so I sent her down there to learn how to use the machine.

Q. Did you go and learn it yourself, or did you just learn from her, and that was –

A. I learned from her, the manual, and then the way I use the machine is not electrodermal screening. I do a different technique.

Q. Is the nurse still working with you?

* * * *

[3178] two, we check for antithrombin antibodies. We do a whole different blood cascade, because these patients have different coagulopathies. They can't get better unless their fibrinogen goes below 300 usually.

In some people with Chronic Fatigue Syndrome you might see fibrinogens around 600 or even higher, and it can be environmental, genetics. There is different causes for it. It affects organisms.

Q. So you put them on Heparin?

A. Not always. There's Nattokinase, an enzyme that lowers fibrinogen, there's curcumin.

Also detoxification of the body of heavy metals will also lower fibrinogen.

Q. So why was she so attached to the machine, rather than to the NAET therapy, because she said don't take my machine away from my doctor, then I won't be able to get my treatment?

A. The reason why, I can scan for hundreds of allergens in a 15-minute office visit, where if I didn't have the machine, I might only be able to scan for maybe half that amount, or even one-third that amount, and I might not find the allergen, so that patient wouldn't get a treatment that day, so the machine saves me a lot of time.

Q. My last question, when any patient comes to [3179] you, are they coming to you as an M.D. or as an NAET practitioner, I mean are they coming to you for everything, looking for –

A. They're coming to me usually from word of mouth. They already know that I'm an M.D. because it's on my door and it's on my business cards that I'm an M.D..

Q. So they come expecting that you will take care of everything for them?

A. No. No, I can't do that, that would be impossible. I mainly specialize in chronic fatigue states and allergies.

Q. So you cannot tell them that you will take care of them the best way you think will be best for them, like –

A. No, some –

Q. – nasal sprays and desensitization or NAET or acupuncture, or –

A. It depends on what their complaint is. If they come in with cardiac problems, they're definitely going to be referred to a cardiologist. If they have problems with sleep apnea, I refer them to a pulmonologist.

So if they come in for allergies, I do avoidance therapy. I give them antihistamines, [3180] steroid nose sprays, tell them to clean up their house and environment, and then I offer them NAET.

DOCTOR UBEROI: I'm done.

JUDGE DeBUSSCHERE: Thank you. It's now an opportunity for follow-up questions by the questions asked by the Panel members.

Mr. Bishin, do you have any follow-up questions?

MR. BISHIN: The only question I have is a question to everybody. My recollection was that Patient 3's testimony, and it may be wrong, is that she was concerned about losing her doctor, not losing the machine.

MS. PAXTON: Did I say that? I think in the end she did say, please don't take the machine away from him.

MR. TENNIS: Yes, she did.

DOCTOR UBEROI: She said please don't take my machine away from him.

MR. BISHIN: I guess I never heard that before.

MR. ARMSTRONG: She said it over and over.

DOCTOR UBEROI: Yes, she did. It was like she was so attached to the machine.

[3181] JUDGE DeBUSSCHERE: Any other questions, Mr. Bishin?

MR. BISHIN: No.

JUDGE DeBUSSCHERE: Mr. Armstrong, question, follow-up questions asked by the Panel members?

RECROSS EXAMINATION

BY MR. ARMSTRONG:

Q. Doctor Ames, let me see if this is your understanding, that assessment is equivalent to diagnosis when dealing with a patient?

A. There is a preliminary diagnosis doctors do when a patient presents with a complaint, and then

there is a final assessment that might be correct or incorrect, but that's what the doctor works on for his plan.

So I start with a working assessment and then I try to finalize it to a final assessment, but the final assessment could be wrong, but we can always do more blood tests to see if it confirms my assessment, or different testing.

Q. Where does the LISTEN machine come in, is it at the preliminary assessment or is it at the final assessment?

A. The LISTEN machine is more of a preliminary [3182] assessment. It's part of a preliminary assessment.

Q. If it's part of a preliminary assessment, don't you go straight to treatment with NAET?

MR. BISHIN: Be a little clearer, Counsel.

Q. I'm trying to find out where the LISTEN machine is in the scheme of your assessment. You're saying it's more in the preliminary assessment, but I think in your testimony – correct me if I'm wrong on this – that once you assess using the machine, which is quicker than using the vials, you go straight into treatment, which is NAET, correct?

A. Well, the assessment consists of a detailed patient history. The patient will usually tell me what their allergen is, or I'll be able to figure out from their history.

I also do blood work, okay, and then I do NAET testing using patient samples that they bring in, or the machine, and then I formulate a theory that they might have an allergy by muscle tests. I do kinesiology tests, and if their arm goes weak, then I can presume that they may have an allergy.

Q. Then you go into treatment, correct?

A. Then I go into treatment, and if their symptoms go away, that further helps my assessment. [3183] That tells me that they probably did have that allergy, because their symptoms went away.

Q. Okay. I think one of the board members asked you about the EAV system, Electroacupuncture Volt –

A. Voll, according to Doctor Voll.

Q. You were talking about making antigens, and you said that the LISTEN device can make vials, correct, did I get that correct?

A. The LISTEN machine can make antigens.

Q. How do you, as a medical doctor, know that it's correct and accurate, how do you know that device is making correct vials?

A. The reason I know that is because since I'm very skeptical, I have the patients bring in real foods or real pollens, and I'll type in milk, and they will bring in a glass of milk, and they get the same response with kinesiology testing.

The only time I would not get the same response might be house dust, because their house dust might have cat hair in it, for instance, the machine might have a different read, or molds, for instance. The machine holds about 80 different molds, because we know there's thousands of different molds, some haven't even been discovered, but besides

* * * *

AMES v. WASHINGTON STATE DEPARTMENT OF HEALTH MEDICAL QUALITY ASSURANCE COMMISSION

On Petition for Writ of Certiorari to The Supreme Court of the State of Washington
NO. 80644-6

OBJECTIONS, ARGUMENTS, RULINGS, AND COLLOQUIES AMONG PRESIDING OFFICER AND COUNSEL

Clerk's Certified Report of Proceedings
1985-86, 2123-24, 2134-38, 2137-38, 2140, 2167-69, 2243-44, 2263-68, 2519-20, 2533-2535, 2542-45, 2547-49, 2551, 2556, 2569, 2575-76, 2648-49, 2680, 3019-20, 3200, 3205, 3213, 3217

[1985] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD DAY 1

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

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REPORTED BY JEAN ERICKSEN, CCR

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[2123] doctors are using it for, is that what you're saying?

Q. Yes.

A. What's your question?

Q. The question is if the item is not approved by the FDA or doctors you know, would you still use it for an alternative use? I'm saying aspirin is not approved. You can't use aspirin for any medical purpose in the United States, but you want to use it for another purpose.

MR. BISHIN: You can't use it or you can?

MR. ARMSTRONG: You cannot use it for headaches.

A. Doesn't that already say that aspirin is illegal for any doctor to prescribe?

Q. There are no doctors that use aspirin for headaches, that's my example, nobody uses it for any medical purpose whatsoever.

MR. BISHIN: Your hypothetical is aspirin is not being legally marketed?

Q. And you were going to use it for a different purpose than headache. Would that be an authorized use as a medical practitioner?

A. I would not use aspirin in that case.

Q. You would not. Okay, so if I understand you [2124] clearly, if it's not an approved product or a drug, you would not use it for a different use?

MR. BISHIN: Objection –

A. That's not what you said.

JUDGE DeBUSSCHERE: One second, Doctor. Objection to what?

MR. BISHIN: He said he would not use it for a different use, what different, different from what?

JUDGE DeBUSSCHERE: I'll sustain the objection, I'm not sure – objection sustained. The question is vague.

MR. ARMSTRONG: Maybe I'm just not being clear. I'll move on to another aspect of it.

Your understanding of off-label use, Doctor, is that it's something that needs to be approved, it can be used for alternative use for what it's approved for.

A. To use it for another use?

Q. As an general term. I'm just using it as a general term.

A. Yes.

Q. If the item is not approved, then off-label use doesn't apply, does it?

A. If the item is not approved by what

* * * *

[2134] Q. Look down at the bottom right-hand side, where it talks about inside range, outside range and reference.

A. I don't know where you're looking.

Q. Same document, the right side at the bottom.

MR. BISHIN: Your Honor, I'm objecting to this entire line of questioning. It has nothing to do with this case. There is nothing that's complained about lead or lead testing or any treatment for lead, or anything of that sort. It's completely irrelevant to this case.

JUDGE DeBUSSCHERE: Mr. Armstrong, I assume you were talking about the Department's case here on allergies. I thought maybe you were pursuing this on the vein that he was, his treatment with regard to allergies.

MR. ARMSTRONG: Yes, that is part of it. The Department's case is on his treatment with patient 1, period, not allergies only, all of the things he did. The patient's complaint was based on his treatment with Doctor Ames, not the LISTEN device of Doctor Ames. It was on all of his visits.

One of the things that the patient is going to testify about is metal toxicity and Doctor Ames' tests, what tests he didn't conduct, and [2135] whether that was above or below the standard of care, according to medical judgment.

MR. BISHIN: He's not going to testify over my dead body. That is not in the Statement of Charges, Your Honor. The regulations that govern this proceeding are very specific about specifically stating the factual basis on the Statement of Charges, and that is not in the Statement of Charges.

We did not prepare a defense to anything leading to that, although counsel is telling us that this is about the entire treatment, everything that went on.

That's not what the Statement of Charges is about. Everyone here can look at the Statement of Charges and see what the Statement of Charges refers to. It refers to this device and to the muscle testing that went on, and to some statement allegedly made, and to the FDCA implications of this particular device.

There is nothing about lead testing or any other kind of treatment, or anything else in the Statement of Charges.

MR. ARMSTRONG: Your Honor, may I respond?

JUDGE DeBUSSCHERE: You may respond.

[2136] MR. ARMSTRONG: Contrary to what counsel is alleging here, paragraph 1.13 of the Statement of Charges talks about the different tests that Respondent ordered, urine, blood and hair analysis tests. That is in the Statement of Charges. Clearly the evidence that is going to be presented will address those factors.

What the Department is alleging is that everything that is listed in the Statement of Charges falls under the negligent practice, and falls below the standard of care.

It doesn't tell you exactly every single detail, because the Statement of Charges doesn't need to do that. We just need to give the Respondent a general basis of what our charges are.

JUDGE DeBUSSCHERE: Okay. The charge is based on the Respondent's use of the LISTEN device, and that is unprofessional conduct as alleged in RCW 18.130.184. There is no allegations here that he, and I put that in my pre-hearing order, that his use of the hair analysis was unprofessional conduct.

MR. ARMSTRONG: If you look at 2.2.

JUDGE DeBUSSCHERE: You said that all of these, some of these alleged facts are conclusions of law. They're not facts at all, and so I cannot, the [2137] way the charges are written alleges that the Respondent committed unprofessional conduct using this machine, this LISTEN device, and particularly in his diagnosing and treating food allergies, this patient's allergies.

There's no other allegations of unprofessional conduct regarding any other mistreatment. The fact and the allegations that the Respondent ordered urine, blood and urinalysis tests is not notice that he committed unprofessional conduct under RCW 18.131.184 on that alone, and I said that in my pre-hearing order.

You yourself said in your opening statement that this is a matter of food allergies, whether or not there was unprofessional conduct with food allergies.

I thought your line of questioning that to do with Doctor Ames, questioning him in regards to providing treatment for food allergies, not the fact that he is going to be charged for, I think you were talking about lead poisoning. That point wasn't alleged and that is not part of the statement of charges here.

If he was charged with lead poisoning for this patient it should have been stated in the [2138] Statement of Charges.

MR. ARMSTRONG: Would you like me to respond?

JUDGE DeBUSSCHERE: You don't need to respond. I made a ruling. The objection is sustained.

MR. ARMSTRONG: Well, I'd like to make an offer of proof.

JUDGE DeBUSSCHERE: You may make an offer of proof.

MR. ARMSTRONG: On the record, under 2.2 in the Statement of Charges, 1.1 through 1.13 are the factual allegations. It says in 2.2 that –

MR. BISHIN: Your Honor, I object. This is not an offer of proof, this is further argument. An offer of proof is an offer of evidence. You're showing the tribunal what evidence you would have introduced if you had been allowed to do so. This is just further argument and it's typical of what counsel does, continually re-arguing and wasting everybody's

time, arguing and re-arguing the same point. This has been going on throughout this entire proceeding.

JUDGE DeBUSSCHERE: Mr. Armstrong, Do you have your offer of proof?

* * * *

[2140] have not changed one bit of our evidence, it's just that he is uncomfortable with how the question is coming out.

MR. BISHIN: I object again. This is not an offer of proof. Even if it were an offer of proof, it's not necessary. What he's pointing to is the Statement of Charges.

The Statement of Charges is on the record, it's right there. An appellate court can see the Statement of Charges without any statement or argument by counsel.

JUDGE DeBUSSCHERE: I have made my ruling. Lead toxicity is not part of the charges, as I have stated in the Statement of Charges. Next question.

Q. Doctor Ames, I want to go back to the LISTEN device itself, and how you use it. You don't use it as an EDS, Electrodermal screening, you don't use it for that purpose?

MR. BISHIN: I object, asked and answered.

MR. ARMSTRONG: I'm trying to get an undertanding.

JUDGE DeBUSSCHERE: It has been asked and answered.

* * * *

[2167] Paxton, do you have questions?

MS. PAXTON: I do, but I want clarity first from you, JUDGE DeBUSSCHERE.

JUDGE DeBUSSCHERE: Okay.

MS. PAXTON: I want to go back to the First Amended Statement of Charges, because I never did get clarity, and the attorneys may say asked and answered, but I'm sorry, that doesn't go for me, and so excuse me, gentlemen, but I have to ask this again.

In 2.2 it talks about the facts alleged in Paragraphs 1.2 through 1.14. as that which constitutes unprofessional conduct, so I need help once again, to understand why you excluded 1.13 as not part of that which constitutes unprofessional conduct.

JUDGE DeBUSSCHERE: I didn't exclude 1.13 as a fact. It was a fact that was alleged, but the allegations alleged that there was conduct that was unprofessional under RCW 18.131.84, incompetence, negligence, malpractice with results causing injury to a patient, which creates an unreasonable risk that the patient may be harmed.

The fact that the Respondent ordered urine, blood, blood tests, hair analysis tests is a [2168] factual allegation, but there is insufficient facts there

to notify the Respondent that the fact that he ordered a urine test is unprofessional conduct, or the fact that he ordered a blood test is unprofessional conduct, or the fact that he ordered a hair analysis, or a combination of those.

There is insufficient information in the Statement of Charges to give notice to the Respondent that such conduct was unprofessional.

The substance of the Statement of Charges references that the patient used the LISTEN device, and such conduct was unprofessional. If I were to allow, if the Statement of Charges had more information, in fact, stated that the Respondent's conduct in giving blood tests or urine tests or hair analysis, such conduct created a certain kind of harm or was below the standard of care in the allegations, there would be sufficient notice for the Respondent to be able to defend himself against those allegations.

At this point in time the document itself is insufficient to give notice to the Respondent to defend himself, to do discovery, cross-examination to prepare for this case by the Statement of Charges, so that's the reason why I made that ruling.

* * * *

[2243] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

In The Matter of the License To Practice as a Physician and Surgeon of: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD

VERBATIM TRANSCRIPT OF PROCEEDINGS
DAY 2

(Filed Oct. 15, 2004)

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[2263] ***Patient 1 – By Dr. Uberoi***

We'll tolerate this for a little bit. Then, we may have to go see about it. Go ahead.

Q (By Dr. Uberoi) He didn't tell you what the benefit or reasoning was for the kelation therapy?

A The benefit, as I understood it –

JUDGE DeBUSSCERE: Excuse me. I don't think we can hear. Let's go off the record.

(Pause in the proceedings.)

Back on the record.

We were able to stop that intervening noise from adjacent rooms.

Go ahead, Dr. Uberoi. You were asking questions.

DR. UBEROI: I was asking if Patient 1, whether he was told anything about benefits or side effects or risks of kelation therapy.

A The benefits, as I say, were explained to me to be linked with the heart and the arteries and that, and actually cleaning out a lot of plaque, things like that. That's kind of what I recall would be the main benefits, kelate the toxins out.

Q Were you told about any risks of kelation?

A No, no, no.

DR. UBEROI: I'm done.

JUDGE DeBUSSCHERE: Ms. Paxton, do you have any questions.

[2264] MS. PAXTON: Just one second, Your Honor. Thank you.

Patient 1 – By Ms. Paxton

EXAMINATION

BY MS. PAXTON:

Q Patient 1, there seems to be some question in terms of what is a focus of this hearing as to your treatment regarding, you know, the allergy issue versus the heavy-metal issue. There's some controversy

about that issue. So I want to ask you some specific questions about that.

MR. BISHIN: Objection, Your Honor. I hear these questions about kelation. You allowed questions about the kelation, about the hair test and all that kind of stuff. But those are not in this case. If this was going to be a case about hair test or kelation, we would have prepared a case for hair test and kelation. It's known from the beginning that this was not what this case was about. Now, we're extending it beyond that. Dr. Uberoi started asking questions about kelation, too.

Now, if it's background, that's fine. But we're going beyond that. Ms. Paxton also seems to want to go beyond that. And I can understand being interested and maybe having opinions on the subject and all of that, but that's not what this case is about. This is a legal [2265] procedure, involves what we call due process of law. Requires notice and opportunity for hearing and the charges that were noticed.

And going on, counsel for the Department of Health has been trying to move this from what the case was always focused on to something else for a while now. But this is highly prejudicial, and I object very strongly to continuing going into this. It's not a matter of controversy as to whether this case is about hair testing, kelation or about allergies and the LISTEN machine. That issue has been resolved. It's not controversial at all. The issue is about the

LISTEN machine and about food allergies and how they were tested for in this particular situation and whether or not the Food, Drug and Cosmetic Act has any application to this particular case.

That's my position, and I believe it's correct, and it will be supported by the record of this entire proceeding, going back to the very beginning of the statement of charges.

MS. PAXTON: Can I respond, for a moment, just in terms of the information?

JUDGE DeBUSSCHERE: You mean, as far as asking questions?

MS. PAXTON: No.

[2266] JUDGE DeBUSSCHERE: Do you have a question –

MS. PAXTON: I guess I had a question for you, then.

JUDGE DeBUSSCHERE: Yes.

MS. PAXTON: It is on the record that Patient 1's chart notes from two visits are here and present, and those have been addressed. Therefore, I presume it's acceptable to ask questions from the material that we already have received.

JUDGE DeBUSSCHERE: You can ask questions about the material that is received.

MS. PAXTON: And it's shown in the second visit a plan that Dr. Ames outlined.

JUDGE DeBUSSCHERE: You mean, in paragraph 1.14 of the statement of charges?

MS. PAXTON: No, in the document marked 2, on page one, Exhibit 2, page one, there's a plan.

JUDGE DeBUSSCHERE: You can ask questions about that.

MS. PAXTON: And that's sort of the direction I'm going.

MR. BISHIN: Objection, Your Honor. I want to object very strongly to that.

Of course, you can ask questions from documents on [2267] the record if they are relevant to the issues before this panel. The entire medical record was put in here, in this particular case, so that the panel and the record would be complete and there would be context. But that doesn't mean that you can go into every possible issue that's raised by what's in those records.

This is a case not about the entire treatment that went on here or the entire recommendation or the entire notes, but about particular things that the department chose to talk about in the statement of charges. That's what the case is about.

So of course they can ask questions, as long as they are related to the issues, as long as they are relevant. And anything, anything that's on the record,

Ms. Paxton or anybody else can ask questions about, just as counsel can ask questions about. But when you are pursuing issues about kelation or hair test or anything else that are not what this case is about, then it's irrelevant and it's also prejudicial.

JUDGE DeBUSSCHERE: Ms. Paxton, the reference on 1.13 describes that he had a visit on June 6, the respondent saw Patient 1. Then, 1.14 focuses on the respondent diagnosing food allergies, the use of the LISTEN device. That's what the charges are about.

[2268] But you can ask questions about the plan, you can ask questions. But the context here is within the issue of was his use of that medical device, was it unprofessional conduct under the allegations.

MS. PAXTON: I understand, Your Honor.

JUDGE DeBUSSCHERE: Was it negligence, did he violate federal and state statutes and was it moral turpitude or did he promote for personal gain any unnecessary device, unnecessary or inefficacious device. So that's the issue here. You can ask questions about other things, but put it in the context of that.

MS. PAXTON: Thank you for your clarity.

Q (By Ms. Paxton) I want to ask you, Patient 1, about your treatment for your allergy. Basically, from the tests that we have talked about before, some of the allergies that stood out over others in terms of the numbers.

A Right.

Q You had stated before that you basically had been told by Dr. Ames that you were going to walk out of his office after the second visit and be cured of your egg allergy; is that correct?

A Correct.

Q And that was after what you considered a treatment that occurred in the office?

* * * *

[2519] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent.	Docket No. ___ 02-06-A-1012MD DAY 3

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

HEALTH LAW JUDGE:
ARTHUR E. DeBUSSCHERE

FOR THE RESPONDENT:
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SUNANDA UBEROI, M.D. JANICE PAXTON, PA-C

CABELL TENNIS, J.D.
Public Member

Renton, Washington
January 13, 2004

REPORTED BY JEAN ERICKSEN, CCR

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[2533] reasonable risk of harm to the public.

Now the classifications make a big difference on how the machine is used. If you have an approved device by the FDA, then you can use it. Basically that's it. If you use it for an alternative use other than what is labeled, which is what has been bandied about as off-label use, that happens all the time in the medical field, but if you're not approved you can't have an alternative use, because if you're not approved you have no use.

It's kind of like not being on the playing field. You can't play a different game if you're not even on the field, and that's what the defense is trying to convince this Panel that they can play an alternative use game, and they're not even allowed on the field. It will not work. The FDA confirmed what my argument was, that an approved device can have an off-label use, but an unapproved device cannot, and this device is unapproved.

We looked at the use. We did ask, Mr. Bishin asked Mr. Ogden about the intended use of the device. Well, the FDA looks at the labeling to determine what the intended use was, not what you plan to do afterwards, not five years from now, but how you plan on using it when it's time to sell it. [2534] That's the use that's on the label, and that's what they go by is an objective concrete criteria. It's

not a changing criteria, it's not a range of criteria. You have to have the intended use on the labeling, with the information that goes with it. If you don't have that, you won't pass the muster of the evaluation.

Well, the LISTEN device, based on this labeling saying what it can do, what its capabilities are, did not pass muster with the FDA, which is the only place it must pass the muster in order to be distributed. What makes this even more serious is it shouldn't even be marketed in the United States. If it's not cleared, it shouldn't be marketed. Now people can buy contraptions all day long everywhere, but you can't use them in practice if it's not cleared by somebody who says it's safe and effective.

This device has not been cleared. This device was marketed. This device was received. The device was received by Doctor Ames. He said he bought it in 1997. He didn't buy it overseas. He bought it here. Receiving a device that's not been cleared violates the statute. There's no question about that.

So as Counsel keeps harping on the [2535] burden that the State has, and I agree we have the total burden here, I'm making the argument on two grounds. One I'm arguing that the burden of proof is not clear and convincing. I'm saying it's the preponderance of the evidence, as the statute says, but because of the case law that has come down recently, we do have an indication that it could be, so I'm

asking you, Panel, to look at my statements under a preponderance of the evidence and a clear and convincing evidence, but I'm going to make my comments in the purview of absolutely clear and convincing, so that you will have no problem on either burden, on the fact that he received a device that was not cleared, violating the State and federal statute is clear. It's a hundred percent. There's not even a doubt on that. Whether this device has been proven safe or effective, there's no evidence. Therefore it's clear. That's a hundred percent.

If he had clearance, he would have a document from the FDA. Now the FDA can't just tell you that you're cleared for your device. They have to give you a document, and you must possess that document in order to receive clearance.

I asked Doctor Ames does he have any written proof from the FDA that this machine is safe

* * * *

[2648] care, because they're experts.

Now, as I say, I can't believe that would be upheld today by the supreme court in a case like this where the Commission is not expected to have any kind of expertise on alternative health care, or on these particular devices. They will have general knowledge about medicine, have general knowledge about health care, but they don't have any evidence on this kind of a device, or on the particular use of acupressure with regard to allergies, or a lot of other things.

We do not believe that the courts would uphold that, it just wouldn't make any sense. How could you defend yourself? There's no evidence put on these issues, and it just goes back to the Commission that later on, after they make the decision, find out what standards they applied in that particular case, but forgetting about all that, one thing that you have to keep in mind here is that even though the court in Johnston said that it wasn't necessary to have a standard of care when it's a physician, since the physicians on the Panel could have rejected it and used their own experience, that only went to standard of care. That only went to standard of care. It did not go to any other issue.

[2649] Although the general law is there must be evidence on the record on which the decision is based, even though inferences can be drawn based on general medical knowledge, there must be evidence on the record, and that evidence must be sufficient to support the decision of this commission. That's A, in fairness to the Respondent.

B, it's essential for the courts to be able to review the decision of the commission. You can't review a decision if you don't have evidence in the record to support it. If there is no evidence to support it and it's hidden evidence that the Panel is relying on, then they can't review it, and there is a specific provision of the Administrative Procedures Act says that every single finding of fact must be supported by evidence on the record. There must be evidence on the record.

The only area where an exception has been made is the standard of care, and that standard of care is often viewed as a legal battle. I say that because in order to find a violation against Doctor Ames, you have to find unreasonable risk or actual harm, and there has been no evidence of unreasonable risk or of actual harm. No one has testified to that here. There is speculation that

* * * *

[2680] the evidence that was presented up to this point, after which the Respondent had rested, and the evidence presented by the Department.

Regarding the Respondent's motion to Dismiss, regarding the alleged violation of RCW 130.180, RCW 18.130.180 Provisions 1 and 7, the Commission granted the Motion to Dismiss.

Regarding the provisions RCW 18.130.180, 4 and 16 the Commission denies the Motion to Dismiss.

The Respondent here is now instructed to present evidence in response to the allegations of RCW 18.130.184, RCW 18.130.180, Provisions 4 and 16.

MR. BISHIN: So that's four and 16 that's still in the case?

JUDGE DeBUSSCHERE: Yes.

MR. BISHIN: Now, I'd like to – I'm sorry, Your Honor, are you done?

JUDGE DeBUSSCHERE: Yes, I have reported the decision on the Motion to Dismiss.

MR. BISHIN: I'd like to raise a couple of issues, procedural issues. One of my telephone witnesses should probably be called soon, in order to be sure that we get him on, but there is another matter that I want to raise and I don't want to have it waived by my calling this witness.

* * * *

[3019] STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

IN THE MATTER OF THE LICENSE TO PRACTICE AS A PHYSICIAN AND SURGEON OF: GEOFFREY S. AMES, M.D. License No. MD00026961, Respondent.	Docket No. 02-06-A-1012MD DAY 5

VERBATIM TRANSCRIPT OF PROCEEDINGS

(Filed Oct. 22, 2004)

A-P-P-E-A-R-A-N-C-E-S

HEALTH LAW JUDGE:

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Public Member

Renton, Washington
February 10, 2004

REPORTED BY JEAN ERICKSEN, CCR

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[3200] during their deliberations.

Okay, so we'll go into recess.

(A recess was taken.)

JUDGE DeBUSSCHERE: We're on the record.

It's now an opportunity for closing argument. This is in the matter of the license to practice as a physician and surgeon of Geoffrey Ames.

Mr. Armstrong, go ahead. You have about 25 minutes.

* * * *

CLOSING ARGUMENT

BY MR. ARMSTRONG:

I want to thank the panel for their indulgence in this case. Knowing that we have a whole bunch of doctors in this state that we could be going after, why is the Department going after Doctor Ames for his use of the LISTEN?

It's a few words why. We don't know if the machine is safe, and neither does he. That's why we're going after Doctor Ames.

And to determine this you have a lot of witnesses that were here determining whether he committed misconduct under the rules, and it's going to come down to credibility. A lot of things were said, and most of them were facts, as to who do you

* * * *

[3205] the treatment of allergies.

Doctor Ames said he never treated Patient 1. It's really curious, again, that the treatment that Patient A described was exactly the same as Patient 3, the exact treatment, the same thing, where he was on his stomach, while he was on his back, and using that machine.

Doctor Ames said today he never used any device on him, but the patient remembered a black, some kind of device on his back thumping him. He remembered it was different than the one that was sitting right beside him, but even Doctor Ames confirmed that he had a manual, so electronic, so Doctor Ames' own rebuttal confirmed what the patient said, not what he said, but what the patient said.

We have asked Doctor Ames and all his witnesses, can the LISTEN machine diagnose? No. Can it cure? No. Why do you use it? It helps me. It makes me faster, more effective, more comprehensive. To do what? You're either using it to diagnose or cure; otherwise, it has no use. The Department yesterday, it has no use, which is why it's inefficacious, which is why it's unknown, and it's why the FDA hadn't cleared it.

He mentioned, Doctor Ames mentioned that

* * * *

SUPERIOR COURT FOR BENTON COUNTY
STATE OF WASHINGTON

GEOFFREY S. AMES, M.D., Petitioner, v. WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMN., Respondent.	NO. 04-2-01837-1 **PETITION FOR REVIEW** (Filed Aug. 16, 2004)

Petitioner Geoffrey S. Ames, M.D., by and through his attorneys, Law Offices of William R. Bishin, Inc., P.S., hereby petitions for review of a final order, an order denying reconsideration of that order, and all previous orders adverse to him entered in the proceeding below by Respondent Medical Quality Assurance Commission.

1. IDENTITY OF PETITIONER

Petitioner Geoffrey S. Ames, M.D., an alternative physician providing health care based on the principles of acupuncture, acupressure, homeopathy and other nontraditional forms of health care, practices and resides in Benton County, Washington with a mailing address of 750 Swift Blvd. No. 1, Richland, WA 99352.

2. IDENTITY OF ATTORNEY FOR PETITIONER

William R. Bishin, Inc., P.S. by William R. Bishin, Esq., WSBA No. 8386, represents Petitioner in this matter and has a mailing address at 1404 East Lynn, Seattle, WA 98112.

3. IDENTITY OF AGENCY WHOSE ACTION IS AT ISSUE

The agency whose action is at issue is the Washington State Department of Health Medical Quality Assurance Commission ("MQAC"), 310 Israel Road S.E. Tumwater, WA 98501.

4. AGENCY ACTIONS AT ISSUE

The Agency actions at issue are the Findings of Fact, Conclusions of Law and Final Order ("Final Order"), dated May 30, 2004 and served June 4, 2004, the Order Denying Petition for Reconsideration, dated July 18, 2004 and served by mail on July 19, 2004, and all other orders and rulings entered by Respondent in the course of the proceedings below to the extent they were adverse to Petitioner, including the order denying constitution of a panel including alternative physicians and the order excluding the majority of Petitioner's proposed witnesses.

The Final Order finds that Petitioner was guilty of unprofessional conduct under 18.130 RCW – i.e., negligence and promotion for personal profit of an

inefficacious modality – in that he used a device which it found to be inefficacious in the assessment and treatment of an allergy of a particular patient. The Order suspends and then stays the suspension of Petitioner's license on the condition that he refrain from using the device, levies a $5,000 fine and enacts a program of monitoring for five years, ostensibly to assure that the device is not used in Petitioner's practice.

The Order Denying Petition for Reconsideration rejects petitioner's claim that the Final Order is devoid of evidentiary support, is an abuse of power by orthodox physicians with respect to an alternative practitioner, and flagrantly and lawlessly disregards controlling Supreme Court authority and statutory mandate.

5. PARTIES IN PRECEDING ADJUDICATIVE PROCEEDINGS

(RCW 34.05.546)

There were no such parties, other than the Department of Health and the Commission, insofar as it is a separate entity as represented by the Attorney General.

6. FACTS DEMONSTRATING THAT PETITIONER IS ENTITLED TO OBTAIN JUDICIAL REVIEW

The Order directly, substantially, and lawlessly, deprives Petitioner of liberty and property not only by inhibiting his successful practice of alternative health care but also by stigmatizing him with a record of a suspended license that will seriously affect his ability to practice in any form, all in violation of 34.05 RCW, 180.130 RCW, and other statutes and of the United States and Washington constitutions and is a final action by an agency covered by the Administrative Procedure Act, 34.05 RCW, and under which Petitioner has an absolute right to seek judicial review. Petitioner contends that he is entitled to relief under several subsections of RCW 34.05.570(3) as more fully described below.

7. REASONS WHY PETITIONER IS ENTITLED TO RELIEF

RCW 18.130.180(4) (second sentence), as its legislative history makes plain, was enacted to protect alternative ("nontraditional') physicians from the prejudices of orthodox, old-line medicine – prejudices which continue to infect the work of medical boards throughout the United States generally and, as this case shows dramatically, of MQAC in Washington, specifically. In addition, the Supreme Court of Washington recently imposed a more demanding evidentiary burden on MQAC because, *inter alia*, of concern that the risk of erroneous MQAC decisions

was greater than the risk of, for example, erroneous court decisions in civil cases involving medical issues. See *Nguyen v. Medical Commission*, 144 Wash.2d 516, 29 P.3d 689 (2001).

With all the respect that is due to a coordinate branch of government, Petitioner contends that the final order entered in this case by MQAC – which contains no practitioners of alternative medicine, either in its regular or its pro tem membership – is not only a breathtakingly arrogant attempt to circumvent both the letter and the spirit of RCW 18.130.180(4) and of the *Nguyen decision*, but a refusal to honor the most elementary principles of evidence law and, at bottom, of due process. The Final Order violates DOH and MQAC regulations, 34.05 RCW, the Administrative Procedure Act ("APA"), as well as 18.130 RCW, the Uniform Disciplinary Act ("UDA"), other statutes and the constitutions of the State of Washington and of the United States.

The Final Order finds that Petitioner in the course of providing an alternative form of care for allergies was guilty of negligence creating an unreasonable risk of harm and of promoting an inefficacious health care device and modality. The Department of Health, however, was unable to produce any evidence to establish harm of any kind, let alone "unreasonable harm." Nor did it produce evidence of inefficacy or any of the other distinguishing elements of the statutory violations charged. *Nguyen* requires that MQAC orders be supported by

clear and convincing evidence, but as to essential elements of the two charges of unprofessional conduct upheld by the MQAC panel in this case, it bears emphasis that there was no evidence at all, let alone substantial or clear and convincing evidence. In addition, the panel disregarded uncontroverted and incontrovertible evidence in medical records that the Department itself introduced, records which directly contradict essential findings in its Order.

The flagrant disregard of evidentiary rules establishes that the panel in this case was intent on prohibiting the use of an alternative modality in which it did not believe, based only on the prejudices of its members against alternative care, and irrespective of the evidence. In so doing the panel unapologetically ignored controlling rules of procedure and proof, DOH and MQAC regulations, the APA, the UDA and other statutes, and the requirements of the state and federal constitutions. The panel thus not only entered an order that was illegal, it displayed illegal and unconstitutional prejudice against Petitioner, demonstrating that it was not qualified to decide this case dispassionately. Among other things, it thereby engaged in unlawful decisionmaking and showed itself to be improperly constituted. All of this was in violation of the APA, the appearance of fairness doctrine and the constitutions of the State of Washington and of the United States.

The panel erred when it refused to dismiss all charges after the close of the Department's case even though it was clear that the Department had failed to

offer evidence to support a violation of the UDA. The panel erred when it entered the Final Order, and it erred when it refused to reconsider that order after Petitioner expressly pointed out for the last of several times the fatal evidentiary flaws in the Department's case.

The Final Order on its face is defective because it does not satisfy specific requirements of 34.05 RCW regarding the contents of such orders and does not provide the support in evidence and reasoning that the statute requires. If, as Petitioner contends, the Department failed to present evidence that could support the legal and factual findings in this case, it is, of course, not surprising that the Order does not set forth the support that the APA requires.

The Final Order finds a violation that was not charged, thereby violating Department of Health and MQAC regulations, the APA and the constitutions of the United States and the State of Washington.

The Final Order was entered after a hearing in which Petitioner was not permitted to call witnesses to testify to the efficacy of his allergy treatments and of his use of kinesiology in conjunction with use of the challenged device, thereby denying Petitioner the right to present his case and to establish his defense, all in violation of DOH and MQAC regulations, the APA and the constitutions of the United States and Washington. The orders denying him these and other rights to introduce relevant evidence violated the

same regulations, statutes and constitutional provisions and are challenged on this appeal as well.

The Final Order instituted sanctions that are an abuse of discretion, requiring monitoring of Petitioner that is unwarranted, arbitrary and capricious, and calculated to deter Petitioner from engaging in legal alternative health care modalities because of the uncontrolled supervisory and monitoring discretion which the Order gives MQAC to inspect and oversee his practice for at least five years.

The Final Order was entered by a panel which contained no physicians or other health care providers who practice alternative medicine, after Petitioner moved for inclusion of one or more such practitioners in the panel prior to the hearing. On the other hand, comments at the hearing betrayed the panel's prejudice against alternative practice. The Final Order either itself or in connection with the other unlawful acts and omissions of the Department and the panel thus violated the appearance of fairness doctrine, the APA, the UDA, and the due process protections of state and federal constitutions.

Among other things, the Final Order violates freedom of expression, due process, equal protection, personal autonomy and other rights protected by the constitutions of this State and of the United States.

The Order Denying Petition for Reconsideration is objected to on the same grounds as the Final Order.

Among other things, Petitioner is entitled to relief under RCW 34.05.570(3), because "(a) The order, or the statute or rule on which the order is based, is in violation of constitutional provisions on its face or as applied; . . . (c) The agency has engaged in unlawful procedure or decision-making process, or has failed to follow a prescribed procedure; (d) The agency has erroneously interpreted or applied the law; (e) The order is not supported by evidence that is substantial when viewed in light of the whole record before the court [nor, *a fortiori*, by clear and convincing evidence], which includes the agency record for judicial review, supplemented by any additional evidence received by the court under this chapter; . . . (g) A motion for disqualification under RCW 34.05,425 or 34.12.050 was made and was improperly denied or, if no motion was made, facts are shown to support the grant of such a motion that were not known and were not reasonably discoverable by the challenging party at the appropriate time for making such a motion; (h) The order is inconsistent with a rule of the agency . . . [and the agency has not explained] the inconsistency by stating facts and reasons to demonstrate a rational basis for inconsistency; . . . [and] (i) The order is arbitrary or capricious."

Because the transcript of the hearing and the voluminous record in the proceeding below have not yet been prepared, Petitioner also seeks relief for all other prejudicial errors which the transcript and the record show to have occurred, on the grounds that he

is entitled to relief for any errors that were prejudicial to him or his case.

8. RELIEF REQUESTED

Petitioner requests that the Court reverse the Order in its entirety and dismiss the proceeding below or in the alternative reverse and remand to the Commission with instructions to act in accord with the Court's decision and to dismiss the proceeding.

DATED: August 14, 2004

LAW OFFICES OF
WILLIAM R. BISHIN, P.S.

By /s/ *William R. Bishin*
William R. Bishin
WSBA No. 8386

CERTIFICATE OF SERVICE

The undersigned caused the foregoing Petition for Review to be served upon Respondent Medical Quality Assurance Commission and the Attorney General by arranging for its delivery to them on August 16, 2004 at the following addresses:

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August 14, 2004

/s/ *William R. Bishin*
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COURT OF APPEALS, DIV. III **NO. 248976**

SUPREME COURT OF
STATE OF WASHINGTON

GEOFFREY S. AMES, M.D.,

Petitioner,

vs.

WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMN.,

Respondent.

PETITION FOR REVIEW

(Filed Sept. 4, 2007)

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By: William R. Bishin No. 8386

Certificate of Service
The undersigned served this Petition on Respondent on this date by placing it in the U.S. MAIL addressed as follows:

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September 4, 2007

/s/ *William R. Bishin*

IDENTITY OF PETITIONER

The Petitioner is Geoffrey Ames, M.D., the petitioner below.

OPINION OF THE COURT OF APPEALS

The unpublished opinion of the Court of Appeals in this matter, Ames v. Medical Board, No. 24897-III was filed, by the Court on May 17, 2007. After Petitioner's timely motion for reconsideration, the Court entered an order denying the motion for reconsideration on August 2, 2007. The opinion and order are attached. See Appendix.

ISSUES PRESENTED

The specific issues of constitutional, administrative, professional disciplinary and other, statutory law that this case raises are set out below. But there are issues that deal with the broader supervisory role of this Court in insuring that every person receive due process and that the outcome of every case comports with the Rule of Law. The appellate issues raised by this case arise out of the most brazen, lawless administrative action that counsel for Petitioner has encountered in over forty years of practice and teaching – including the teaching of administrative law – in jurisdictions throughout this country. The case is a frivolous, malicious prosecution, brought to coerce a settlement. It was prosecuted without evidence, yielding a decision, based on a series of patent speculations and ad hoc

factual theories created during and after the evidentiary hearing in this case.

Respectfully, and with a vivid awareness of and concern about the emotional resistance of judges to criticisms of their friends and colleagues on other courts, it must also be said that the agency's lawlessness in this case has been aided, abetted and implemented by the most striking abdication of judicial responsibility that counsel has encountered in the State of Washington, after almost thirty years of practicing here.

In short, the Court of Appeals refused to grant Petitioner the judicial review of agency error, to which he was entitled under the Administrative Procedure Act and the due process and equal protection clauses. As this and other courts have held, because of the needs of the administrative state, judicial review is the only protection against agencies with peculiar opportunities to engage in uncontrolled abuse, because they have been delegated and can combine in abusive ways the legislative, administrative, investigative, prosecutorial and adjudicative powers.

Not only does the Court of Appeals opinion in this case – and the oral, argument which preceded it – suggest that it did not seriously review the evidentiary record, the findings, or Petitioner's brief; not only does that court fail in all but one minor instance to cite even one place in the record which supports its affirmance of agency findings that

Petitioner vigorously challenged; but the Court of Appeals (borrowing not from the record, but from the agency brief) actually creates facts out of whole cloth and shifts the burden of proof to the Petitioner. It not only misstates the facts, but it bases its justification of the agency's conduct on findings that were never made and facts that do not exist. Like the respondent's brief, which it apparently viewed as the only document it need pay any serious attention to, that court also justifies the agency decision, not by defending the reasoning of the agency, but by creating a new, after-the-fact theory. The result is that the statement of charges proceeded on one factual theory, the panel's Order on another, and, the Court of Appeals's on yet another. Compare the allegations in the amended statement with ¶¶ 1.25-1.29 of the challenged Order with pages 10-14 of the Court of Appeals opinion, all of which appear, in the appendix. See Opening Brief ("OB") Appendix and this Appendix.

The outrageous decision of the agency was not surprising, because similar agencies throughout the country have done similar – although not quite as brazen – things in similar cases. But in those other jurisdictions, the Courts would not stand for it, and found a way to thwart the abuse of legislative power. See, especially, *Painter v. Abels*, 998 P.2d 931 (Wyo. 2000), where a medical board attempted to prevent an alternative physician from using a device like the one in this case by attacking her mental health and when that failed by claiming negligence without being able to offer any expert testimony to support

the claim. It is more than ironic that in Washington, where public policy is clearly opposed to the substantive objective which motivated the agency's action, the courts simply deferred to the agency's abuse and then defended it in disingenuous opinions.

There follow some of the specific issues this appeal raises.

1. Was the Medical Commission ("MQAC") panel that issued the Order on appeal correct in ruling that under existing Washington law no expert evidence on the record was necessary to establish the medical, scientific, or technical, facts on which its decision rests, and if the panel was correct, should those decisions, as to that issue, be overruled or limited on due process or other legal grounds?

2. Under WAC 246-11-250, WAC 246-11-260 and WAC 246-11-520, which requires that a statement of charges must contain a "clear and concise statement of the . . . factual basis" of the charges, must the statement set forth the specific facts – including the specific conduct of the respondent – found to constitute unprofessional conduct or is notice pleading sufficient?

3. Did MQAC's failure to specify in the statement of charges facts that it found essential to its conclusion that Petitioner had engaged in unprofessional conduct – including the specific conduct of the respondent which allegedly constitutes such conduct – violate his "due process right to be notified of clear and specific charges and to be afforded an

opportunity to anticipate, prepare, and present" his defense. *In re Romero,* 152 Wash.2d 124, 94 P.3d 939 (2004)?

4. May a physician be found to have engaged in "negligence" under RCW 18.130.180(4) because of a good faith mistake in judgment on one occasion without explicit evidence on the record that the mistake violated a standard of care which makes such a mistake negligence?

5. Under RCW 18.130.180(16) which makes "promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure, or service" "unprofessional conduct,"

(a) is evidence and/or a finding that a device failed to function successfully on one occasion sufficient by itself to support a finding or a conclusion that the device is "inefficacious" within the statute's meaning?

(b) is the use in his practice of an alternative assessment device for which the respondent does not charge and which was not shown to increase his income, "promotion for personal gain" of that device within the meaning of the statute, taken as a whole and considering the consequences?

6. Were the proceedings below taken as a whole so outrageous and inconsistent with due process and the Administrative Procedure Act as to require this Court to lay down specific guidelines for the initiation, and conduct of medical commission hearings, at least

in cases involving alternative physicians and alternative medical, modalities?

7. Did the Court of Appeals and the Superior Court accord the Petitioner meaningful .judicial review of the panel decision in this case – *e.g.*, of his right to a determination of the sufficiency of the evidence under the Administrative Procedure Act and the due process clause?

STATEMENT OF THE CASE

This case arises out of the use by a holistic physician of an assessment device which was found to be inefficacious and its use therefore a violation

* * * *

NO. 80644-6

SUPREME COURT OF
STATE OF WASHINGTON

GEOFFREY S. AMES, M.D.,

Petitioner,

vs.

WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMN.,

Respondent.

PETITIONER'S MOTION FOR RECONSIDERATION

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The undersigned served this Supplemental Brief on Respondent and Amicus on this date by placing it properly stamped in the U.S. MAIL addressed as follows:

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June 24, 2009

/s/ *William R. Bishin*
WILLIAM R. BISHIN

MOVING PARTY AND RELIEF REQUESTED

Petitioner Geoffrey S. Ames pursuant to RAP 12.4 asks the Court to reconsider and vacate or correct its decision and opinion entered on June 4, 2009 on the grounds and for the reasons set forth below.

POINTS OF LAW, FACT, EVIDENCE AND PROCEDURE THAT THE COURT HAS OVERLOOKED OR MISAPPREHENDED

Preliminary Statement

This is the case involving an alternative medical device used by the Petitioner in his allergy medicine practice. Petitioner argued that the Medical Commission Order finding him negligent and otherwise unprofessional for using a device it found to be inefficacious, was not supported by evidence, specifically necessary expert testimony, and that the doctrine that appeared to allow such findings based

only on the Commission's expertise should be disapproved. The Court has now held that the Order was based on expert testimony of the device's creator and an expert on biofeedback, to the effect that the device was not designed or approved for the use Petitioner made of it and that biofeedback machines cannot do what Petitioner does with it.

In doing so, the Court has decided this appeal on grounds – both factual and legal – that were not the grounds cited by the Medical Commission panel that entered the Findings, Conclusions and Order in this case, nor by any party in this case. Even though the Court holds the panel to be an expert body on the medical issues raised, it has interposed its own lay conceptions about, and lay interpretations of, relevant medical and technological evidence, standards, medical and regulatory practices and other facts.

It is not surprising that by taking on the expert function of the Commission in its evaluation of evidence, it misinterpreted the testimony of the two experts it relies on, James Clark and Richard Sherman. It misreads and gives that testimony a different interpretation than the one given by the Commission panel and a weight that the panel and its Order clearly did not give it. In usurping the Commission's expert function the Court has also applied uninformed lay assumptions and conceptions patently inconsistent with the facts of the medical profession, the standards of medical practice and medical science, and the regulation of medical devices. By so doing, the Court has reached a decision

that cannot withstand even minimal critical scrutiny: its holding is literally arbitrary, capricious, and even irrational. The result is to apply to the Petitioner standards that he could not anticipate beforehand and that cannot and will not be applied to other physicians and health care practitioners. By deciding the appeal on grounds that were not advanced in this case until it reached this Court, it has also blind sided Petitioner, depriving him of the right to respond to the case against him. The opinion is itself, therefore, a violation of due process and of equal protection under the State and Federal constitutions.

In addition, the insufficiency of the evidence on which the Court relies and the fact that the Court does not defend the actual rationale of the Commission's Order, but adopts its own rationale for it, suggests that the Court has simply decided – based on its own, non-record, lay experience – that the device in question cannot be used in the way the Petitioner used it. Apparently, because the Court has never heard of a device that could generate homeopathic signals, and because the idea seems so strange and bizarre, based on the Court's experience, it feels justified in relieving the Commission of its obligation to prove that the device was inefficacious for the purpose for which Dr. Ames used it. Either that or it has adopted an inarticulate policy of simply deferring to the Commission, at least with respect to alternative providers, because of the Commission's putative expertise, even as to alternative medical technology. A decision based on such grounds is a

decision based on undiluted lay prejudice. It reflects a lack of familiarity with the history of innovations in medicine and science, all to the prejudice of public policy and scientific progress, as well as to due process, equal protection, and the free inquiry values underlying state and federal protections of freedom of expression.

The Court's opinion also bestows a power on the FDA which was not intended by Congress and which interferes with the FDA's regulatory authority. The opinion gives FDA decisions not to approve a medical device for a particular purpose an authority and scope they were never intended to have and which the FDA may well not want. The opinion, therefore, violates the supremacy clause.

The argument supporting the specific points overlooked or misapprehended by the Court is set forth in the Argument section. For the Court's convenience, Petitioner lists those oversights and misapprehensions together as follows.

1. The opinion makes the mere "off-label" use of a medical device sufficient to establish that a physician has engaged in unprofessional conduct: this was not the ground of the Commission's decision and creates the extraordinary and absurd result of making virtually every physician who sees patients guilty of negligence

2. Neither in Logic Nor In Experience Is It Rational to Hold That A Device Designed For One Purpose, Cannot *Ipso Facto* Be Efficacious For Any Other Purpose

3. The Basis of the Commission's Decision and Findings: The Decision Was Not Based In Any Respect on the Clark or Sherman Testimony

4. The Court's Lay View of the Testimony of Mr. Clark and Dr. Sherman, Which the Commission Did Not Rely On, Led the Court to Misapprehend the Meaning and Significance of That Testimony

ARGUMENT

I. THE OPINION MAKES THE MERE "OFF-LABEL" USE OF A MEDICAL DEVICE SUFFICIENT TO ESTABLISH THAT A PHYSICIAN HAS ENGAGED IN UNPROFESSIONAL CONDUCT: THIS WAS NOT THE GROUND OF THE COMMISSION'S DECISION AND CREATES THE EXTRAORDINARY AND ABSURD RESULT OF MAKING VIRTUALLY EVERY PHYSICIAN WHO SEES PATIENTS GUILTY OF NEGLIGENCE

At page 9 of its opinion, the Court states as follows:

> Substantial evidence leads to the conclusion that Ames was using the LISTEN for purposes for which the machine was not designed or approved. As such no additional expert testimony was necessary to demonstrate the elements of professional misconduct.

The main testimony on which the Court relies in its opinion, it paraphrases as follows on page 8:

> Clark testified that the device was not submitted to the FDA for any diagnosis, treatment, or curing of allergies or any other ailments.

This holding and use of testimony – Dr. Sherman's testimony will be dealt with elsewhere – misunderstands FDA law and practice, specifically, the meaning of not having an FDA approval for a particular purpose. Lack of such approval establishes neither inefficacy nor negligence. There is other testimony of Mr. Clark that the Court could also rely on, but which it does not cite. That testimony will be discussed in Points III and IV, which address the Court's misapprehensions about the evidence the Commission panel actually relied on, and about the meaning of the evidence the Court invokes to uphold the Commission decision.

Our focus here is on the holding that using a machine for a purpose for which it "was not designed or approved" – *i.e.*, an off-label use – by itself establishes unprofessional conduct – *i.e.*, physician negligence and inefficacy of the device. This holding flies in the face of a basic fact of, everyday medical practice brought to the attention of the Court in Petitioner's briefing, but overlooked in the decision process.

In *Buckman v. Plaintiffs Legal Committee,* 531 U.S. 341, 350, 121 S.Ct. 1012, 1018 (2001), the United

States Supreme Court states that "off-label usage of medical devices" is "the use of a device for some ***other purposes*** than that for which it has been approved by the FDA." (Emphasis added.) Such use, the Court notes is "accepted and necessary" and "courts, several States, and the 'FDA itself recognize the value and propriety of off-label use.'" *Ibid.* In fact, as the Court noted, 21 U.S.C. § 396 protects the right of a health care practitioner" to use a device legally marketed for other purposes "for any condition or disease." *Ibid.*

The decision in the *Buckman* case turned on the Court's concern that using a state cause of action to piggyback onto the FDA's regulation of the marketing of medical devices would "deter off-label use despite the fact that the FDCA expressly disclaims any intent to directly regulate the practice of medicine, . . . and even though ***off-label use is generally accepted.***" (Emphasis added.) This court's opinion also deters off-label use by making the use of a legally marketed device *ipso facto* illegal because it was not "designed or approved" for the off-label use Petitioner made of it. Thus, this Court's opinion as written undermines the FDA's regulatory balance by adding to the consequences of its refusal to approve a device for every possible use it might have and "deter[ring] off label use," contrary to the intent of the FDCA. *Ibid.* at 350, at 1018.

If that is not bad enough, however, the Court's holding creates a rule that makes virtually every practicing physician guilty of unprofessional conduct. As the *Buckman* Court noted in quoting an article on

off-label use, "'Off-label use is ***widespread*** in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA and most courts recognize." *Id.* at 351, at 1019 (Emphasis added.) See Mayo Clinic, *Off-label Drugs and Medical Devices,* mayoclinic.com/health (October 1, 2007) ("Off-label use of drugs or medical devices isn't unusual. By some estimates, ***more than one out of every five drugs*** prescribed in the United States is for off-label use.") (Emphasis added.)

The Court's opinion is apparently based on the lay misconception that because a device has not been approved by the FDA it has been found to be inefficacious. As the Department's own FDA witness testified, this is not true. CR 2412-2414. There are many reasons, usually financial, why a device is not submitted for approval of a particular purpose and even when it is, the unwillingness of the FDA to approve does not mean that it is inefficacious, only that the FDA did not find the evidence submitted sufficient. *Ibid.* It is not a finding that the device cannot do what is claimed, as the *Buckman* decision necessarily implies.

Thus, even if this Court does not reconsider its decision, it should at a minimum rewrite it so that the rationale does not affect off-label use of devices or drugs.

The Court's Rationale and Medical Theory Is Not in the Order Under Review. Finally, the theory that use of a device for a purpose for which it was not

designed or approved is itself negligence and in itself establishes a device to be inefficacious is not to be found in the Commission's Order. This is not surprising since such a theory is indefensible on its face and the Commission had been apprised of the law relating to off label uses.

II. THE COURT OVERLOOKS THE FACT THAT NEITHER IN LOGIC NOR IN EXPERIENCE IS IT RATIONAL TO HOLD THAT BECAUSE A DEVICE IS DESIGNED FOR ONE PURPOSE, IT CANNOT *IPSO FACTO* BE EFFICACIOUS FOR ANY OTHER PURPOSE

Whether a device designed for one purpose can be used for another is a question of fact, not of logic. A book is designed to convey ideas by means of a bound text, but it can be used, among other things, as an object in a still life painting, as a weight to hold down papers, as a door stop, as a blunt object to kill a fly, as something to hold on one's head to practice good posture, as fuel for a fire. By merely establishing that the book was designed

* * * *

NO. 248976

COURT OF APPEALS, DIVISION III
STATE OF WASHINGTON

GEOFFREY S. AMES, M.D.,

Petitioner,

vs.

WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMN.,

Respondent.

ON APPEAL FROM THE SUPERIOR
COURT OF BENTON COUNTY,
THE HON. CARRIE RUNGE PRESIDING

OPENING BRIEF OF PETITIONER (CORR.)

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CERTIFICATE OF SERVICE

The foregoing Opening Brief of Petitioner was filed by mail with the Court on this date and served on respondent herein by depositing a copy in the United States mail first class postage pre-paid on this date and addressed as follows:

Kim O'Neal, Esq.
Assistant Attorney General
Office of Attorney General
1125 Washington S.E.
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July 31, 2006

/s/ *William R. Bishin*
WILLIAM R. BISHIN

PRELIMINARY STATEMENT

This appeal is about a device sometimes used by an alternative physician as part of his procedure for assessing patients with possible allergies. Although a medical commission panel did not find that the physician had deceived or injured anyone, that he had acted in bad faith, or that the device was unsafe, it did rule that using it with a patient was "unprofessional conduct" under RCW 18.130.180(4) and (16). The device, based on Asian and homeopathic medical theories, was, the panel asserted, "inefficacious." Using it was, assertedly, negligence, and charging for the treatment to which it was related constituted "promotion for personal gain" of an "inefficacious" device. The panel suspended the physician's license, stayed the suspension on condition that he refrain from using the device, pay the Commission a $5,000 fine, and submit to regular practice reviews and reports to the Commission.

Petitioner contends that the Commission, believing but unable to prove, that the device could not work, lawlessly disregarded evidentiary norms,

procedural safeguards and the language of the relevant statutory scheme in order to suppress its use. The evidence and the findings were not only insufficient, they were grossly insufficient and it is difficult not to conclude that the panel's decision was a cynical manipulation of evidence, reasoning and statutory language to reach a result that could not be defended even by conventional medicine's professional and scientific standards, let alone by those the law insists upon. The decision poses a severe threat to alternative medicine generally, because if the "method" of prosecuting and deciding this case were upheld it could be used by any panel of conventional practitioners to suppress any alternative approach that has not been expressly identified and protected by the legislature. It would effectively allow the Commission to make its own law in cases involving alternative physicians and disregard the legislative policy favoring choice and patient freedom in those areas where conventional medicine has failed to meet patient needs. Thus, it is imperative that this Court not only overturn the decision, but that it do so in language that notifies the Commission that it will not tolerate an agency's playing fast and loose with procedural due process, no matter how truly the agency believes that the ends justify the means.

ASSIGNMENTS OF ERROR

The Commission panel erred in entering the following findings of fact, because a reasonable fact-finder could not have found that they were supported

by *clear and convincing* evidence (or even by a preponderance) and, as to many of them, they had not been pleaded as required by Department of Health ("DOH") regulations, the Administrative Procedure Act (34.05 RCW) and due process:

1. ¶ 1.7, first sentence.

* * * *

they are not only insufficient, but grossly so and so disingenuous as also to be arbitrary and capricious. *See e.g.*, ***Olmstead v. Department of Health***, 61 Wn.App. 888, 895, 812 P.2d 527 (Div. 1,1991). Similarly, but more obviously, although under ***Johnston***, DOH need not, at least in cases like ***Johnston***, introduce specific evidence of the assertedly applicable conventional standard of care, it is not relieved of the burden of introducing clear and convincing evidence of every other element constituting alleged unprofessional conduct. For example, ***Johnston*** does not relieve DOH of the need to establish that Dr. Ames's conduct created an "unreasonable risk" of harm to a patient, and that the device in this case was "inefficacious" and "promot[ed] for "personal gain."

Thus, ***Johnston*** and ***Davidson*** stand only for the proposition that the panel members in making a negligence determination may use the general, background knowledge that they have acquired through their training and experience to evaluate and draw inferences from the evidence that was introduced. *E.g.*, ***Brown***, at 105 ("agency may use its experience

and specialized knowledge to evaluate and draw inferences from the evidence"). There must still be clear and convincing evidence of record from which the rational, fair-minded fact-finder can infer the necessary ultimate fact. Compare, *e.g.*, ***Franz v. Board of Medical Quality Assurance***, *supra* at 142-143 (record must disclose the basis of the panel's expert opinion).[16]

II. THE EVIDENCE THAT DR. AMES WAS NEGLIGENT FOR USING THE LISTEN IS GROSSLY INSUFFICIENT, INDEED, DISINGENUOUS

A. Why There is a Special Need For Clear and Convincing Evidence in this Case

The Commission charged Dr. Ames with unprofessional conduct for using the LISTEN in assessing P1. It thus had the burden of production and persuasion as to each fact on which it based this quasi-criminal charge. WAC 246-11-520 ("the burden is on the department to prove the alleged factual basis of the initiating document"); ***Nguyen v. Medical***

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[16] ***Johnston***'s holding about standard of care evidence – which was not the primary holding in that case – was cursory, incidental, almost casual, and the Court did not appear to be aware that its position was a minority one, raising serious due process and other problems. If Dr. Ames were forced to challenge it in the Supreme Court that it would not likely survive. See *Martin v. Sizemore*, 78 S.W.3d 249 (Tenn.Ct.App. 2001) for the reasons.

Quality Assurance Commission, 144 Wn.2d 516, 29 P.3d 689 (2001). Because it is a quasi-criminal charge involving severe professional consequences, because the public invests in and needs the services of highly-trained health care practitioners, and because error is likelier on charges adjudicated by part-time agency members combining judicial, legislative and executive functions, and acting "as investigator, prosecutor, and decisionmaker" (***Painter v. Abels***, 998 P.2d 931 (Wyo. 2000), see footnote 3, *supra*.), Washington requires that DOH's proof be "clear and convincing" ***Nguyen***, *supra*.

* * * *

NO. 80644-6

SUPREME COURT OF THE STATE OF WASHINGTON

GEOFFREY S. AMES, M.D.,

Petitioner,

v.

WASHINGTON STATE HEALTH DEPARTMENT AND MEDICAL QUALITY ASSURANCE COMMISSION,

Respondent.

RESPONDENTS' ANSWER TO PETITION FOR DISCRETIONARY REVIEW

ROBERT M. MCKENNA
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I. IDENTITY OF RESPONDENTS

The Respondent is the Washington State Health Department ("Department") and Medical Quality Assurance Commission ("Commission").

II. OPINION OF THE COURT OF APPEALS

Division Three of the Court of Appeals affirmed the Final Order of the Medical Quality Assurance Commission in this matter in its opinion No. 24897-III dated May 17, 2007, and denied Dr. Ames' motion for reconsideration on August 2, 2007. Those opinions are contained in the Appendix to Dr. Ames' Petition for Discretionary Review.

III. COUNTERSTATEMENT OF ISSUES PRESENTED FOR REVIEW

1. Under settled Washington law, are Commission members entitled to use their expertise to consider the evidence and draw inferences from facts presented in the record when deciding whether a physician has provided treatment below the standard of care?

2. Where the charging document notified Dr. Ames of the patient, the two specific dates of treatment, and the statutes allegedly violated, did the charges meet the statutory and constitutional due process requirements for notice?

* * * *

RCW 18.130.180 §§ (1), (4), (7), (16)

18.130.180. Unprofessional conduct

The following conduct, acts, or conditions constitute unprofessional conduct for any license holder or applicant under the jurisdiction of this chapter:

(1) The commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person's profession, whether the act constitutes a crime or not. . . .

. . . .

(4) Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed;

. . . .

(7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice;

. . . .

(16) Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure, or service;

. . . .

WASHINGTON ADMINISTRATIVE CODE
§§ WAC 246-11-250, 246-11-260, 246-11-520

SECTION II
INITIATING ACTIONS

WAC 246-11-250 Form and content of initiating documents. (1) Initiating documents shall include a clear and concise statement of the:

(a) Identity and authority of the person issuing the document;

(b) Factual basis for the action or proposed action set forth in the document;

(c) Statutes and rules alleged to be at issue;

(d) Identity of the party against whom the action is taken or proposed to be taken;

(e) Action or proposed action or penalties, including the statutory or rule authority for those actions or penalties;

(f) Signature of the person issuing the document and the date signed; and

(g) Method by which an adjudicative proceeding may be requested.

(2) Initiating documents shall be accompanied by the following documents:

(a) Notice that the respondent may defend against the action or proposed action; and

(b) Form for requesting adjudicative proceeding.

(3) Initiating documents shall be served as described in WAC 246-11-080.

* * * *

WAC 246-11-260 Amendment of initiating documents. (1) Prior to the hearing date, initiating documents may be amended subject to the following conditions:

(a) Amended initiating documents shall meet the requirements of WAC 246-11-250(1);

(b) Amended initiating documents shall be accompanied by the documents described in WAC 246-11-250(2);

(c) Whenever amended initiating documents are issued, a new interval for response will begin, as described in WAC 246-11-270, unless the respondent requests the time periods set by the original initiating document; and

(d) Issuance of amended initiating documents ends all obligations of the parties under the prior initiating documents.

(2) On the hearing date, the initiating documents may be amended subject to the following conditions:

(a) The documents may be amended upon motion of the state;

(b) The documents may not be amended without the approval of the presiding officer; and

(c) Upon motion of a party or upon his/her own initiative, the presiding officer may grant a continuance on all or part of the matter if necessary to afford the respondent an opportunity to prepare a defense to the amended documents.

* * * *

WAC 246-11-520 Standard of Proof. The order shall be based on the kind of evidence upon which reasonably prudent persons are accustomed to rely in the conduct of their affairs. In all cases involving an application for license the burden shall be on the applicant to establish that the application meets all applicable criteria. In all other cases the burden is on the department to prove the alleged factual basis set forth in the initiating document. Except as otherwise provided by statute, the burden in all cases is a preponderance of the evidence.

* * * *

RCW 34.05.452(5)

34.05.452. Rules of evidence – Cross-examination

. . . .

(5) Official notice may be taken of (a) any judicially cognizable facts, (b) technical or scientific facts within the agency's specialized knowledge, and (c) codes or standards that have been adopted by an agency of the United States, of this state or of another state, or by a nationally recognized organization or association. Parties shall be notified either before or during hearing, or by reference in preliminary reports or otherwise, of the material so noticed and the sources thereof, including any staff memoranda and data, and they shall be afforded an opportunity to contest the facts and material so noticed. A party proposing that official notice be taken may be required to produce a copy of the material to be noticed.

* * * *

RCW 34.05.461

(1) Except as provided in subsection (2) of this section:

. . . .

(3) Initial and final orders shall include a statement of findings and conclusions, and the reasons and basis therefor, on all the material issues of fact, law, or discretion presented on the record, including the remedy or sanction and, if applicable, the action

taken on a petition for a stay of effectiveness. Any findings based substantially on credibility of evidence or demeanor of witnesses shall be so identified. Findings set forth in language that is essentially a repetition or paraphrase of the relevant provision of law shall be accompanied by a concise and explicit statement of the underlying evidence of record to support the findings. The order shall also include a statement of the available procedures and time limits for seeking reconsideration or other administrative relief. An initial order shall include a statement of any circumstances under which the initial order, without further notice, may become a final order.

(4) Findings of fact shall be based exclusively on the evidence of record in the adjudicative proceeding and on matters officially noticed in that proceeding. Findings shall be based on the kind of evidence on which reasonably prudent persons are accustomed to rely in the conduct of their affairs. Findings may be based on such evidence even if it would be inadmissible in a civil trial. However, the presiding officer shall not base a finding exclusively on such inadmissible evidence unless the presiding officer determines that doing so would not unduly abridge the parties' opportunities to confront witnesses and rebut evidence. The basis for this determination shall appear in the order.

(5) Where it bears on the issues presented, the agency's experience, technical competency, and specialized knowledge may be used in the evaluation of evidence.

. . . .

* * * *

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21 U.S.C. § 360c(E)(i)

Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 360(k) of this title. However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the ""Director"") may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing. . . .

SUPERIOR COURT FOR BENTON COUNTY
STATE OF WASHINGTON

GEOFFREY S. AMES, M.D., Petitioner, v. WASHINGTON STATE HEALTH DEPARTMENT MEDICAL QUALITY HEALTH ASSURANCE COMMN., Respondent.	**NO. 04-2-01837-1** **PETITIONER'S OPENING BRIEF**

CERTIFICATE OF SERVICE

The undersigned caused the foregoing Petitioner's Opening Brief to be served upon Respondent by arranging for its delivery on April 18, 2005 at the following addresses:

Kim O'Neal, Esq.
Assistant Attorney General
Office of Attorney General
1125 Washington S.E.
Olympia, WA 98504

April 18, 2005

/s/ *William R. Bishin*
WILLIAM R. BISHIN WSBA NO. 838B

* * * *

using acupuncture with unprofessional conduct for checking pulses – perhaps the most common

diagnostic technique used in that Asian specialty – in order to determine the patient's energetic balance. The Commission could then call no witnesses as to the harm or inadequacy of the practice, confining itself to putting on testimony that the licensee in fact did use pulse readings to diagnose his patients. The deficiencies in the evidence would be made up by the supposed expert knowledge possessed by the panel members.

Johnston and the other cases each contain statements that DOH need not introduce specific expert testimony of the standard of care when it prosecutes a licensee for negligence, since a panel of licensees is presumed to know the standard of care. *Johnston* and the other decisions, insofar as they dealt with this issue, were not based on full briefing, do not discuss contrary authority, do not discuss the due process and judicial review issues involved and appear to be unaware that their position is a minority one.[footnote omitted] For a discussion of this and of the many issues the *Johnston, Davidson* and *Brown* opinions do not address, see, *e.g., Martin v. Sizemore*, 78 S.W.3d 249, 271 (Tenn.Ct.App.2001); *Drew v. Psychiatric Sec. Rev. Bd, supra*; and *Painter v. Abels, supra*, a case relied upon

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opportunity to seek a continuance. No such motion was made at any time.

The requirement of notice and an opportunity to defend is elementary to every lawyer and judge.

E.g., State v. Perry, 96 Wn.App. 1, 5, 975 P.2d 6, 8 (Div. 1 1999). The APA requires that the notice of a hearing must include "a short and plain statement of the matters asserted by the agency" or if the agency is unable to state all of the facts, a "statement of the issues involved." RCW 34.05.434(2), (3). The agency was not unable. The record taken as a whole shows it was in possession of the relevant facts. But neither a plain statement of the facts relating to the matters discussed below nor a statement of the issues relating to them appeared even in the amended statement of charges. See generally, *e.g., Olmstead v. Dept. of Health*, 61 Wn.App. 888, 892, 812 P.2d 527, 530 (1991); *Cooper v. Board of Prof. Disc.*, 134 Idaho 449, 4 P.3d 561, 567 (Id. 2000); RCW 34.05.434(2), (3);

The amended statement of charges alleged in sum as follows: that on June 6, 2001, Dr. Ames had seen Patient One, who complained of chronic fatigue. ¶1.13. Dr. Ames "ordered urine and blood tests and hair analysis." *Ibid.* On July 10, 2001, Patient One had another visit in which the test results were discussed and Dr. Ames told him that the blood tests showed a number of food allergies. ¶1.14. Dr. Ames then tested Patient One's muscles by applying pressure to his extended arm and Patient One was able to hold his arm up. Ibid. Dr. Ames then allegedly had him hold a brass rod connected to the LISTEN in his hand while the doctor "typed in 'eggs' into the device. Ibid. When Patient One was then tested a

second time, he was unable to resist. Ibid. This, Dr. Ames allegedly said, showed

* * * *